# EPA Jacket 71355-2 Vol.1

OCT -8 2004

Olivia Laird Agent for. NV CID Lines SA 501 South Lincoln Avenuc Sterling VA 20164-2024

Subject:

CID 2000

EPA File Symbol 71355-E

Your Letter from Hill Top Research, Inc. Dated March 12, 2004

In EPA's letter dated August 15, 2003, the Agency indicated that "The amended officacy data (MRID 459188-01) does not support the use of the product CID 2000 as a disinfectant with bactericidal activity when tested against Salmonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load (i.e., horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution." The efficacy science review indicated the reason for the denial in section VI (Conclusions): "The laboratory has failed to provide neutralization data demonstrating that Letheen Broth is an effective neutralizer for the product. Neutralization and toxicity evaluation data were provided against Staphylococcus aureus but not against Salmonella choleraesuis. Otherwise, no growth was observed in the subcultures of the carriers tested against three lots of the product."

In the March 12, 2004 letter from Hill Top Research, Inc. the lab indicated that section 7. Neutralization of DIS/TSS-2 permits companies to either use secondary subcultures or to re-inoculate the test carriers with low levels of the test microorganism to demonstrate neutralization. Hill Top Laboratories elected to conduct secondary subcultures to demonstrate neutralization. Your lab also chose to prove neutralization using an organism completely unrelated to the test organism. The test organism is Salmonella choleraesuis, and Staphylococcus aureus was used in the subculture test. It is for this reason that the study was rejected. The Agency's interpretation of DIS/TSS-2 does not support the use of an unrelated test organism when demonstrating neutralization.

Following is an excerpt taken from EPA's Series 91: Product Performance Guidelines, Subscries 91A: Public Health Usc Antimicrobial Agent Product Performance Test Guidelines:

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#### 71355-E, pg. 2

- (vii) Neutralization. For each antimicrobial product, procedures must be employed that will preclude residual effects of the active ingredient(s) in the subculture medium. A specific medium capable of neutralizing the antimicrobial effects of a product (whenever one is known) should be employed prior to the microbiological assay. However, evidence must be submitted to demonstrate that the neutralizer employed inactivates the active ingredient(s) and does not posses any antimicrobial activity itself. Some of the recommended methods described in this section rely solely upon the selection of an appropriate subculture medium to neutralize the antimicrobial effects of certain general types of chemical compounds (active ingredients). In lieu of chemical neutralization, it must be documented that appropriate subculture techniques have been employed that preclude residual carryover of active ingredient(s). To document the absence of residual effects of the active ingredient(s) in the subculture medium, one of the following procedures should be conducted:
- (A) Secondary subcultures must be performed to demonstrate that antimicrobial effects are overcome. Both the primary cultures and secondary subcultures should be incubated and checked for growth. Results [(+) or (-) growth] for both primary cultures and secondary subcultures should be reported with the test results; or
- (B) At the conclusion of the incubation period specified or employed in the method, the primary culture medium with test carrier must be inoculated with approximately 10 microorganisms/ml of the <u>specific organism undergoing</u> testing (this value should be documented by actual plate counts) and re-incubated for the specified period to demonstrate that the subculture media was capable of supporting growth.

To re-iterate, because you did not use the <u>specific organism undergoing testing</u> in the neutralization procedure you have failed to provide neutralization data which demonstrates that Letheen Broth is an effective neutralizer for the product. Please refer to the Agency's deficiency letter dated August 15, 2003 to determine what steps need to be taken to continue processing your application.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703) 308-6237.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Management Branch I

Antimicrobials Division (7510C)





To: Karen Leavy/DC/USEPA/US@EPA

t0/10/01 11:58 AM

Subject: Re: Egg Hatching Sanitization claims for labeling (EPA File Symbol

Number 71355-E)

Hatching egg claims are considered FDA regulated drug claims. You should contact Dr. Woodrow Knight at FDA's Center for Veterinary Medicine for additional information. His number is 301-827-0219. If Dr. Knight can't help you, he may be able to direct you to the proper individual.

From an EPA standpoint, the product would need to be a food contact surface sanitizing agent in addition to having the approval from FDA.

Michele Karen Leavy

Karen Leavy

10/09/01 02:07 PM

To: Michele Wingfield/DC/USEPA/US@EPA, Emily

Mitchell/DC/USEPA/US@EPA, Marshall

Swindell/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA

CC:

CC:

Subject: Egg Hatching Sanitization claims for labeling (EPA File Symbol Number

71355-E)

Ladies,

Marshall wanted me to check with you concerning Egg Sanitization claims that appear on this particular product labeling.

Question #1) Does the registrant have to generate Non-food contact sanitization data for the use pattern of the Egg

Sanitization that appears on the product labeling?

Question #2) Does FDA control through regulation this use pattern of the Egg Sanitization claim that appears on the

product labeling?

Your help is greatly appreciated!!!!!

**KML** 



U.S. ENVIRONMENTAL PROTECTION AUENCY Office of Peatinide Programs
Antimitrobials Bivisios (75100)
1200 Peansylvania Avenue, N.W.
Machington, D.C. 2046D

EPA Rug. Numbec:

Date of Issuance:

71355-2

MOV 2 3 2005

NOTICE OF PESTICIDE:

. Registration Re-registration Term of Issuance:

CONDITIONAL

Name of Posticide Ptoduct:

Kickstart

(under FIFRA, as Amended)

Hame and Address of Registrant (include 2)P code):

Cid Lines NV/SA Waterspoorstraat 2-13 8900 Ieper Belgium



On the hasis of information turnished by the registrant, the above named posticide is hereby registered/receptishere under the Federal Insacticide, Fungicide, and Rodenkicide Act, as amended.

Registration is in to tay to be construed as an undersement or recommendation of this product by the Augmey. In order to protoco health and the environment, the Administrator, on his solida, may at any time suspend or descot the registration of a periodic in accordance with the Aut. The acceptance of any name is consection with the taylor received an advance of any name is consection with the taylor received an advance of the research of the

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4, or as required by registration review under FIFRA Section 3(g).
  - 2. Make the following labeling changes:
  - Revise the EPA Registration Number to read, "EPA, Reg. No. 71355-2".
  - b. Place the appropriate Establishment No. on the product labeling.

Signature of Approving Official: Muin dell

MOV 2 3 7005

Marshall Swindell, Product Manager, Team 33,

Regulatory Management Branch I, Antimicrobials Division

PPA Form \$570-6

page 2 EPA Reg. No. 71355-2

3. Submit three copies of a final printed production label.

The Confidential Statement of Formula dated October 21st, 2005, is acceptable.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the accepted label is enclosed for your records.

If you have my questions concerning this letter, please contact Karen M. Leavy-Munk at 703-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33

Product Manager 33

Regulatory Management Branch 1 Antimicrobial Division(7510C)

Enclosure

# < KICKSTART >

# CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active Ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients

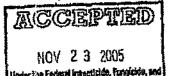
26.5% 4.9% <u>58.6 %</u> 100.0%

# KEEP OUT OF REACH OF CHILDREN DANGER

FICKSTART is effective against :

Bacteria :	dilution
Staphylococcus aureus (ATCC 6538)	1:200
Salinonella cholerasuis (ATCC 10708)	1:200
List iria monocytoganes (ATCC 15313)	1:200
Myc oplasme gallinarum (ATCC 19708)	1:200
Salmonella Choleraesuis serotype onteritidis (ATCC 13078)	1:200
Pseudomonas Aeruginosa (ATCC 15442)	1:21)0
Fungus (on environmental surfaces) :	
Aspergillus fumigatus (ATCC 36507)	1:128
Virus (on environmental surfaces):	
Infectious Bursal Disease of Chickens (ATCC D78,VR-2041)	1:200
Nevicastle Disease (Spelas strain 539016)	1:200
Aviuπ Reovirus (MERIAL SELECT strain 2408)	1:200
Marok's Disease virus (Spafas strain)	1:2:00

/vil tests in the presence of 400ppm AOAC hard water and 5% organic load,



Under the Federal Intectición, funcición, sed Rodentición, Aci es estended, for the pestición, registered under FPA Reg. No. 7/355

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	<ul> <li>Call a polson control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OF	Take off contaminated clothing
CLOTHING	<ul> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
·	Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> </ul>
:	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
FINHALED	Move person to fresh air.
	<ul> <li>If person is not breathing, call 911 or an ambutance, then give artificial respiration, preferably mouth- to- mouth, if possible.</li> </ul>
·	Cail a poison control center or doctor for further treatment advice.
;	NOTE TO PHYSICIAN :
Prol	pable mucosal damage may contraindicate the use of gastric lavage

#### APPLICATION:

In order to disinfect non-food contact surfaces of farm, animal and poultry housing facilities and equipment thoroughly mix one fluid ounce of this product with one and a half gallons of water (1:200). Follow all of the cleaning and application instructions indicated in each of the sections below. In order to affectively kill fungi (i.e., Aspergillus fumigatus) you must use 1 fl. oz of this product par one gallon of water ditulion (1:128).

### DIRECTIONS FOR USE:

It is a violation of federal faw to use this product in a manner inconsistent with its labeling.

- 1. Farm equipment and animal housing buildings (poultry & turkoy grow-out houses, laying houses, swine production and housing, barns and large animal buildings):
  For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steet, copper, aluminum, finished wood, viryl, plastics, glazed tiles, sealed brick walls, sandwich panels and feeding/drinking equipment:
- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, valls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturiste all surfaces with disinfecting colution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ aquipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other leeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfucting solution should be made daily.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return KICKSTART to the original container after it has been removed. Avoid all contaminants, especially dirt, caulatic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition in case of decomposition, isolate container, douse container with cost water and dirties KICKSTART with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container of of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden paltets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing toots. Keep combustible and organic materials away. Flush apilled material with large

quantities of water. Untilluted material should not enter confined spaces.

Disposal of posticide: Pesticide wastes are acutely hazardous, improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law, if these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal anvironmental taws, rutes, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulation; pagnicies should be contacted by prior to disposal. KICKSTART, which is to discharged, should be disposed of its trazurdous waste after contacting the appropriate local, state, or Foderal agency to determine proper procedures.

Disposal of container: Friple rinse. Then offer for recycling or puncture and dispose in a sanitary lundfill. Disposal by incheretion, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: This product at it a use dilitation is compatible with stainless steel and atuminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before pro peoding with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturar Warrants (a) that this product conforms to the chemical description on the tobet; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and of the statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tasts have not been made on all varieties or in all states or vitted tail conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and filness for particular from the use of this product in any manner which is inconsistent with the label directions, warrings or cautions. Buyer's exclusive remarks and manufacturer's or seller's exclusive tiability for any and all claims, losses, damages, or injurios resulting from the use or handling of this product, whether or not such liability for any and all claims, losses, damages, or injurios of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages are itting from the use or handling of this product.

EPA Reg. Nº : 71355-

EPA Est. Nº: 71355-BEL-001

NET CONTENTS: 1 - 5 gallon(s)

BATCH N\*: EXPIRY DATE:



Produced by:
CID LINES NV/SA
Waterpoortshart 2 - B 8900 JEPER
BELGIUM - EUROPE
Phone: 0f1 32 57 2/7877
Fax: 0f1 32 57 2/7879
www.ciglines.com - info@cldlines.com

MCCIEPTED

NOV 2 3 2005

Under the Federal Insecticióe, Funglidde, and Rodenticide, Act as amended, for the pesticide, registered under EPA Reg. No. 77365-2

2. Hatcheries :

Hatcheries: Remove atl animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disin ecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities) :

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces it visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allowite air dry. A potable water rinse is required for all surfaces that come into contact with food.

4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

DANGER, CORROSIVE. Causes trreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. KtCKSTART is not combustible; however, at temperatures exceeding 156°F, decomposition occurs reteasing oxygen. The oxygen released could initiate combustion.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Etinithation System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

ACCEPTED

NOV 2 3 2005

Under the Federal Insecticide, Fungiciae, and

Rodenicide, Act as amended, for the pesticide, registered under EPA Rog. No. 71,333-22

# Laird's Regulatory Consultants, Inc

Over 32 years Experience and Expertise in The Regulation of Pesticide Products

September 9, 2005

Mr. Marshall Swindell, PM 33
Environmental Protection Agency
Regulatory Management I
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: KICKSTART

**EPA FILE SYMBOL 71355-E** 

Revised labeling per our phone conversation

Karen Leavy reviewer

Dear Mr. Swindell:

Please find attached hereto, five (5) copies of the revised label for the product label referenced above. Per our conversation, we have removed the reference to E. Coli until the lab has made a correction to the data pertaining to this organism. We have also changed the ATCC Number for Salmonella Cholerasuis to 10708 per your request.

Thank you for your assistance in this process.

Should you have additional questions or concerns please don't hesitate to let me know as soon as possible.

Sincerely,

Olivia D. Laird

President/Agent

dagussa,

Vincent Catry Cid Lines NV Waterpoortstraat 2 B-8900 (eper Belgium Degusas Corporation 379 Interpace Parkway P.O. Box 677 Parsippany, NJ 07054-0677

Direct: Fax: (973) 541-8053 (973) 541-8040

Kathisen, Nese@degussa,com www.degussa.com

Dear Mr. Catry,

Degussa Corporation has received your request to be allowed to cite Product Chemistry data used by Degussa in the FIFRA registration of Peraclean 5. The number assigned to the report in which this data is contained is MRID 44506501. Degussa Corporation does not seek any compensation for your use of this data.

I recommend that you include a copy of this letter with your product registration documentation and associate this document with your data matrix, EPA Form 8570-35.

Best regards,

Kathleen Nese

Manager of Product Safety

Degussa Corporation - Product Regulatory Services

√Michael Lev.) Product Manager

Degussa Corporation - Bleaching and Water Chemicals

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#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 2 0 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Olivia Laird CID Lines NV/SA Waterpoorstraat 2-B 8900 Ieper Belgium

Mail to: Laird's Regulatory Consultants, Inc.

Shenstone Estates 17804 Breamar Place Leesburg, VA 201780-7046

Subject: Kickstart

EPA File Symbol Number 71355-E Your Application June 10<sup>th</sup>, 2005 EPA Received Date June 10<sup>th</sup>, 2005

The following application, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, is unacceptable for the following reasons:

#### EFFICACY

As per our letter of June 23<sup>rd</sup>, 2005, neutralization data has not been submitted for the organism, Escherichia coli. Delete the claim for E. coli from the product labeling OR Provide the neutralization data for our review and acceptance.

Please note: This data must be submitted before the claim can be accepted.

However, the submitted data(MRID # 465694-01) were adequate to support AOAC Letheen Broth as a neutralizer when used against Kickstart at a dilution of 1:256 for Salmonella choleraesuis.

Please note: The data has been found to be acceptable at this time; however, it is not the standard method of neutralization that is performed in the AOAC use dilution test wherein 10 organisms/mL are added to the post neutralized sample and observed for growth.

#### LABELING

The proposed label claims that the product, Kickstart, is an effective disinfectant against Salmonella choleraesuis at a dilution of 1:256 and a contact time of 10 minutes. This claim is acceptable based on previously and currently submitted data(MRIDs 465694-01 and 459188-01).

Please note: In the future, the laboratory must conduct neutralizer effectiveness testing as described in the AOAC Use Dilution Test, wherein, 10 organisms/mL are added to a post neutralized test sample instead of an inoculated carrier.

The proposed label claims that the product, Kickstart, is an effective disinfectant against Salmonella chloeraesuis at a dilution of 1:256 dilution and a contact time of 10 minutes. Neutralization data must be submitted before this claim can be accepted.

A copy of the review is enclosed for your review.

The Agency reserves a full label review until the above discrepancies have been clarified.

The product may not be lawfully distributed in interstate commerce until the above discrepancies have been clarified.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)





4858944

Environmental Protective Agency Marshall Swindell Product Manager 33 Regulatory Management Branch I Antimicrobial Division Washington DC 20460

leper, May 31, 2005

Subject:

KICKSTART - CID 2000

EPA File symbol n°: 71355-E

Dear Mr. Swindell.

In reply to your letter, dated Jan 13, 2005 and your letted, dated Oct 8, 2004, we hereby supply supplemental neutralizer and toxicity control data for efficacy against Salmonella Cholerauis.

The amended efficacy data (MRID No. 459188-01) was not accepted for reasons of lack of neutralizer control on Salmonella Cholerasuis. With this report we wish to provide this supplemental data. Additionally, we have also amended the label with an efficacy claim against this organism, together with the broad spectrum claim on top of the label.

Yours Sincerely,

Vincent Catry Regulatory Affairs DP#: (318421) Decision #: 216261

# **DATA PACKAGE BEAN SHEET**

Date: 04-Aug-2005 Page 1 of 1

# \* \* \* Registration Information \* \* \*

Registration: 71:	355-E - CI	D 2800		
Company: 71	355 - CID	LINES N.V		
Risk Manager: RIV	1 33 - Mars	shall Swindeli - (703) 308-6341 Room#	CM-2 308H	
Risk Manager Reviewer: Kai	ren Leavy	KLEAVY		
Sent Dale: 14-	Jun-2005	Calculated Due Da	ie 08-Oct-2005	Edited Due Date:
Type of Registration: Pio	duct Reg	stration - Section 3		
Action Desc: (18	8) ADDIT	ONAL USE;NEW REGISTRATION;OL	D INGREDIENT:ME	E-T00
Ingredients: 000	0595. Hydr	rogen peroxide(20%)	*	
		the second control of		
	\$ } } ;	* * * Data Package In	formation * *	ik fik
Expedite:	Yes	No Date Ser	nt: 21-Jun-2005	Oué Back;
OP ingredient: 600	0595, Hydr	ogen peroxide		
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Organization: AD / PSB		24-Jun-2005	8/0/05	Last Possible Science Due Date: 05-Jul-2005
Team Name: EET	*ATTACACHE	24-Jun-2005	04-Aug-2005	Science Due Date: 08-Sep-2005
wiewer Name: Wawzysko	o, Marcie	27-3un-2005	29-Jul-2005	Sub-Data Package Due Date; 24-Aug-2005
Contractor Name:	91934			
		* * * Studies Sent for Re	eview * * *	
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PLEASE REVIEW THE EFF METHOD(MRID NO. 465694 9-18-05, ADMIN DUE DATE	4-01); PR(C	DPOSED LABELING AND LAST STAN	FECTIVENESS AN IPED LABEL IS EN	ID EVALUATION FOR AOAC USE-DILUTION CLOSED;FQPA, ACTION CODE 188, EET,

Decision #: 216261

DP#: (318421)

# **DATA PACKAGE BEAN SHEET**

Date: 21-Jun-2005
Page 1 of 1

\* \* \* Registration Information \* \* \*

Registration:	71355-E - C	D 2000	•
Company:	71355 - CID	LINES N.V.	un.
Risk Manager:	RM 33 - Ma	shail Swindeil - (703) 308-6341 Room# CM-2 308H	
Risk Manager Reviewer:	Karen Leav	KLEAVY	
Sent Date:	14-Jun-200	Calculated Due Date: 08-Oct-2005 Edited	Due Date:
Type of Registration:	Product Re	istration - Section 3	
Action Desc:	(188) ADDI	IONAL USE;NEW REGISTRATION;OLD INGREDIENT;ME-TOO;	<del>-</del>
tngredients:	000595, Hy	rogen peroxide(20%)	***
	000000000000000000000000000000000000000	* * * Data Package Information * * *	
Expedite:	🔘 Yes 🌑	No Date Sent: 21-Jun-2005	Due Back:
DP Ingredient:	000595, Hy	trogen peroxida	_
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DP Title:			<b></b>
CSF included:	• Yes	No Label included: • Yes ( No Parent DP#:	····
Assigned T	o	Date in Date Out	
Organization: AD / F	rse	6/24/05 Last Possible Science	Due Date: 05-Jul-2005
Team Name: EET		6/24/25 \$3/05 Science	Due Date: 5/8/65
Reviewer Name:	ncie	729 105 Sub-Data Package	Due Date: 9/8/65  Due Date: 8/24/65
Contractor Name:		, , , , , , , , , , , , , , , , , , , ,	
		* * * Studies Sent for Review * * *	
	* * * At	ditional Data Package for this Decision * * *	
	E.A.III. — A.E.	* * * Data Package Instructions * * *	
PLEASE REVIEW THE METHOD(MRID NO.46 9-18-05, ADMIN DUE I	55694-01); Pi	STUDY ENTITLED, "NEUTRALIZER EFFECTIVENESS AND EVALUATION FOF ROPOSED LABELING (1997) STORY OF THE STORY OF T	



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION PESTICIDES
AND TOXIC SUBSTANCES

July 29, 2005

### MEMORANDUM

Subject:

Efficacy Review for Kickstart, EPA Reg. No. 71355-E;

DP Barcode: D318421

From:

Marcie Wawzysko Tidd, Microbiologist Marcie Tidd
Product Science Branch
Antimicrobials Division (7510C)

Nancy Whyte, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Thru:

Aritimicrobials Division (7510C)

Michele E. Wingfield, Chief Product Science Branch

Antimicrobials Division (7510C)

To:

Marshall Swindell PM 33 / Karen Leavy-Munk

Regulatory Management Branch I Antimicrobials Division (7510C)

Applicant:

CID LINES NV/SA

Waterpoortstraat 2 B 8900 IEPER Belgium, Europe

#### Formulation from the Label:

Active Ingredient(s	<u>%</u>	by wt.
Hydrogen Peroxide	9	26.5%
Peroxyacetic Acid.	***************************************	4.9%
	**************************************	
	1	00 0%

#### I. BACKGROUND

The product, Kickstart® (EPA Reg. No. 71355-E) is a new product developed by CID LINES N.V. for use as a broad spectrum disinfectant (bactericide, virucide, fungicide). The applicant is submitting additional data in response to requests made in Agency letters dated January 13, 2005 and October 8, 2004. The submitted study was conducted by Hill Top Research, Inc., located at Main & Mill Streets in Miamiville, Ohio 45157.

The data package contained a letter from the applicant to the Agency (dated May 31, 2005), one study (MRID No. 465694-01) with Statements of No Data Confidentiality Claims and Compliance with GLP, and the proposed product label.

#### **II. USE DIRECTIONS**

The product is designed to be used for disinfecting hard, non-porous surfaces on farm equipment, animal housing buildings, floors, walls, pens, stalls, chutes, cages, feeding/drinking equipment, handling/restraining equipment, vehicles, hatchers, setters, trays, racks, carts, tables, chick boxes, and animal cages. The product may be used on hard, non-porous surfaces such as steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, and sealed brick walls.

Directions on the proposed label provide the following information regarding preparation and use of the product as a disinfectant on farm equipment and animal housing buildings: Thoroughly clean surfaces with soap or detergent. Rinse with water. Saturate surfaces with disinfection solution using spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Rinse feeding and watering appliances with potable water before reuse.

The proposed label also includes directions for the disinfection of hatcheries, food processing plants, and trucks and other vehicles.

#### III. AGENCY STANDARDS FOR PROPOSED CLAIMS

#### Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis ATCC 10708 (for effectiveness against Gramnegative bacteria), Staphylococcus aureus ATCC 6538 (for effectiveness against Grampositive bacteria), and Pseudomonas aeruginosa ATCC 15442 (representative of a nosocomial pathogen). [180 carriers per sample; a total of 540 carriers] To pass performance requirements, tests must result in killing in 59 out of each set of 60 carriers to give a 95% confidence level. These agency standards can be found in DIS/TSS-1.

#### Supplemental Recommendations: Neutralization

For each antimicrobial product, procedures must be employed that will preclude residual effects of the active ingredient(s) in the subculture medium. A specific medium capable of neutralizing the antimicrobial effects of a product should be employed prior to the microbiological assay. Some of the Recommended Methods rely solely upon the selection of an appropriate subculture medium to neutralize the antimicrobial effects of certain general types of chemical compounds (active ingredients). However, to document absence of residual effects of the active ingredient(s) in the subculture medium, the following testing is necessary: (i) secondary subcultures must be performed to demonstrate that antimicrobial effects were overcome, or (ii) at the conclusion of the incubation period specified or employed in the method, the primary culture medium with test carrier must be inoculated with approximately 10 microorganisms/ml of the specific culture under test (documented by actual plate counts) and re-incubated for the specified period to demonstrate that the subculture medium was capable of supporting bacterial growth.

#### IV. SUMMARY OF SUBMITTED STUDIES

MRID 465694-01 "Neutralizer Effectiveness and Toxicity Evaluation of AOAC Use-Dilution Method for Kickstart" by Kathieen A. Baxter. Study conducted by Hill Top Research, Inc., HTR Study Number 04-123608-106. Study completed May 27, 2005.

This study was conducted to determine the effectiveness of a neutralizer to inactivate the test agent and to determine the lack of toxicity of the neutralizer to the test system. One lot (Lot No. 405073) of the product was tested, and AOAC Letheen Broth was used as the neutralizing agent. One sterile stainless steel carrier was exposed to a 1:256 dilution of the test substance for 10 minutes at 20±1°C. Another carrier was inoculated with a 48-54 hour old culture of Salmonella choleraesuis (ATCC 10708) and exposed to 10mL of sterile purified water for 10 minutes at 20±1°C. After exposure, the carriers were transferred to a single tube of 10 mL neutralizer medium and mixed. After 30 minutes, both carriers were transferred to secondary subculture tubes of 10 mL neutralizer. All tubes were incubated for 48 hours at 37±2°C and examined for the presence or absence of growth.

#### V. RESULTS

Growth was seen in both primary and secondary subculture tubes for both replicates.

#### VI. CONCLUSIONS

The submitted data (MRID 465694-01) were adequate to support AOAC Letheen Broth as a neutralizer when used against Kickstart® at a dilution of 1:256 for Salmonella choleraesuis. This data is supplemental to an earlier study (MRID 459188-01) in which the AOAC use dilution test was performed against this organism without determination of neutralizer effectiveness.

\*\*Please note: The Agency will accept this data at this time; however it is not the standard method of neutralization that is performed in the AOAC use dilution test wherein 10 organisms/mL are added to the post neutralized sample and observed for growth. The method used in this study, involving an inoculated carrier added to neutralizer broth containing a sterile, treated carrier is unorthodox. This procedure will add an extremely high number of organisms to the neutralizer broth, causing uncertainty in the resulting cultures as to whether actual growth is seen, or if the turbidity is due solely to the high number of organisms removed from the carrier surface.

#### VII. RECOMMENDATIONS

1. The proposed label claims that the product, Kickstart®, is an effective disinfectant against Salmonella choleraesuis at a dilution of 1:256 and a contact time of 10 minutes. This claim is acceptable based on previously and currently submitted data (MRIDS 465694-01 and 459188-01).

\*Note: In the future the laboratory must conduct neutralizer effectiveness testing as described in the AOAC Use Dilution Test, wherein 10 organisms/mL are added to a post neutralized test sample instead of an inoculated carrier, for reasons explained above.

2. The proposed label claims that the product, Kickstart®, is an effective disinfectant against *Escherichia coli* at a 1:256 dilution and a contact time of 10 minutes. As discussed in the June 23, 2005 letter from the Agency, neutralization data has not been submitted for this organism. The applicant must submit such data before this claim is acceptable.



## CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active Ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID inert ingredients

26.5% 4.9% <u>58.6 %</u> 100.0%

# KEEP OUT OF REACH OF CHILDREN DANGER

CID 2000 is effective against:

dijution
1:256
1:256
1:256
1:512
1:512
1:512
1:200
1:128
1:384
1:384
1:384
1:384

All tests in the presence of 400ppm AOAC hard water and 5% organic load.

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and genity with water for 15-20 minutes Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
1	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN or	Take off contaminated clothing
CLOTHING	<ul> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
	Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul> <li>Cail a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> </ul>
	<ul> <li>Do not induce vorniting unless told to do so by a poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
······································	NOTE TO PHYSICIAN:
Prob	pable mucosal damage may contraindicate the use of gastric lavage

EPA Reg. Nº: 71355-

NET CONTENTS: 1 - 5 gallon(s)

BATCH N°:



Produced by:
CID LINES NV/SA
Waterpooristraat 2 – B 8900 IEPER
BELGIUM – EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879
www.cldlines.com - Info@cidlines.com

EPA Est. Nº: 71355-BEL-001

#### APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

- Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings)
- 2. Hetchers, Setters, and chick processing facilities
- 3. Food processing plants (sleughterhouses)
- 4. Trucks end other vehicles

#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE, Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. KICKSTART is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE:**

it is a violation of federal law to use this product in a manner inconsistent with its labeling.

- 1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):
  For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, sandwich panels and feeding/drinking equipment:
- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent end rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate bulldings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovets, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disInfecting solution should be made daily.



Produced by:
CID LINES NV/SA
Waterpoortstreat 2 – B 8900 IEPER
BELGIUM – EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879
www.cidlines.com - info@cidlines.com

EXPIRY DATE:

#### 2. Hatcheries :

Hatcheries: Remove atl animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly solled.

#### 3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return CID 2000 to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute CiD 2000 with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden patiets.

Procedures for leak of spitt: Stop leak if this can be done without risk. Shut off Ignition sources; no flemes, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undituted material should not enter confined spaces.

Disposal of pesticide: Pasticide wastas are acutaty hazardous, improper disposal of excess pesticide, spray mixture or finsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into sultable treatment system in accordance with att local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary tandfill. Disposal by incineration, or if allowed by state and local authorities, by burning, if burned, stay out of smoke.

Note: This product at its use dilution is competible with stainless steel and eluminum surfaces. It product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of loxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressity excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to repiscement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or sallar be liable for special, indirect or consequential damages resulting from the use or handling of this product



Produced by:
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BELGIUM – EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879
www.cidlines.com - info@cidlines.com

SUBMISSION BAR CODE # 775//O REVIEWER   2114-Munk  CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMEND  PILE SYMBOL/REG NO. 7/355-E FM 33 ACTION CODE / 8  DESCRIPTOR Additional ( ) REQUIRED ( ) NOT REQUIRED  ( ) CHILD RESISTANT FACKAGING: ( ) REQUIRED ( ) NOT REQUIRED  DATE ON APPLICATION BEAR RECEIVE DATE FM RECEIVE DATE  DATE ON APPLICATION BEAR RECEIVE DATE FM RECEIVE DATE  METHOD OF SUPPORT PORMULATORS EXEMPTION  ( ) CITE-ALL ( ) SELECTIVE ( ) SUBMITTED ( ) NOT SUBMITTED  ( ) NOT SUBMITTED ( ) N/A ( ) N/A  REVIEW(S) REQUESTED DATA DATE DUE DATE RETURNED  CHEMISTRY	16261 SURM. DUE DATE 06-25-05	
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JUN 2 3 2005  RESPONSE CODE RESPONSE DATE		-

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

JUN 2 3 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Olivia Laird CID Lines NV/SA Waterpoortstraat 2-B 8900 Ieper Belgium

Mail to: Laird's Regulatory Consultants, Inc.

Shenstone Estates 17804 Braemar Place Leesburg, VA 20178-7046

Subject: Kickstart

EPA File Symbol 71355-E

Your Application Dated February 23rd, 2005

EPA Received Date March 2nd, 2005

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, is unacceptable for the following for the following reasons:

#### **EFFICACY**

The submitted efficacy data(MRID No. 464805-01) do not currently support the use of the product, Kickstart, as a disinfectant with bactericidal activity against Escherichia coli on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (horse serum) for a contact time of 10 minutes at a 1:256 dilution. Provide the results of neutralizer effectiveness testing, which was apparently conducted under study assigned Hill Top Research Study No. 01-109138-106.

The submitted efficacy data (MRID No. 464805-01) do not support the use of the product, Kickstart, as a fungicide against Aspergillus fumigatis (ATCC 10894) on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load(horse serum) for a contact time of 10 minutes at a 1:256 dilution.

However, the submitted efficacy study (MRID No. 464805-03) supports the use of the product, Kickstart, as a disinfectant with fungicidal activity against Aspergillus fumigatis(ATCC 36607) on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (heat inactivated fetal bovine serum) for a contact time of 10 minutes at a 1:128 dilution. No growth was observed when the product was tested against two lots of the product. Viability controls were positive for growth. Sterility controls did not show growth. Fungistatic streaks exhibited no growth.

The submitted efficacy data support the use of the product, Kickstart, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:384 dilution:

Avian Reovirus MRID No. 464805-04
Marek's disease virus MRID No. 464805-02
Newcastle disease virus MRID No. 464805-05

Complete inactivation (no growth) was indicated in all dilutions tested. Cytotoxicity was not observed. Recoverable virus titers of at least 10 were achieved.

#### LABELING

The proposed label claims that the product, Kickstart, is an effective disinfectant against Escheria coli on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes, is unacceptable. The submitted data do not currently support this claim. Delete the following efficacy claim from the product labeling or provide the results of the neutralizer effectiveness testing in order to support this efficacy claim.

The proposed label claims that the product, Kickstart, is an effective against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic load for a contact time of 10 minutes when used at the dilutions specified;

Aspergillus fumigatis(ATCC 36607)

Avian Reovirus (MERIAL SELECT strain 2408)

1:384 dilution

Marek's disease virus(Spafar strain)

Newcastle disease virus(Sparas strain)

1:384 dilution

1:384 dilution

The proposed label also includes claims of effectiveness against the following microorganisms:

Staphylococcus aureus(ATCC 6538)
Listeria monocytogenes(ATCC 15313)
Mycoplasma gallinarum(ATCC 19708)
Salmonella choleraesuis serotype enteritidis (ATCC 13076)
Pseudomonas aeruginosa(ATCC 15442)
Infectious Bursal Disease of Chickens(ATCC D78,VR-2041)

The submitted data do not currently support this claim. Delete the following efficacy claims from the product labeling or provide data to support these efficacy claims to the Agency of our review.

Make the following revisions to the proposed labeling, as follows:

On page 1, change"Salmonella chloeasuis" to read "Salmonella choleraesuis.

On page 3, change "Procedures for leak for spill" to read "Procedures for leak or spill".

On page 3, change "regulatory agencies should be contacted by prior to disposal" to read "regulatory agencies should be contacted prior to disposal".

On page 3, change "Kickstart which is discharged, should be disposed....." to read "Dispose of Kickstart.....".

A copy of the review is enclosed for your records.

The Agency reserves a full review until the above discrepancies have been clarified.

The product may not be lawfully distributed in interstate commerce until the above discrepancies have been clarified.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703) 308-6237.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C) DP #: (314158) Decision #: 216261

# **DATA PACKAGE BEAN SHEET**

Date: 20-May-2005
Page 1 of 1

		" " " Kegistration in	ormation *	~ ~
Registration:	71355-E - CID-26	F (Kickstart)		* = 1.400 %*
Сотрапу:	71355 - CID LINE	S N.V.	Not man colorishmet	
Risk Manager:	RM 33 - Marshall	Swindell - (703) 308-6341 Room#	CM-2 308H	
Risk Manager Reviewer:	Karen Leavy KLE	AVY		
Sent Date:	02-Mar-2005	Calculated Due Da	le: 25-Jun-2005	Edited Due Dale:
Type of Registration:	Product Registrati	on - Section 3		
Action Desc:	(188) ADDITIONA	L USE;NEW REGISTRATION;OL	D INGREDIENT;	ME-TOO;
Ingredients:	000595, Hydroger	peroxide(20%)		
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		* * * Data Package In	formation '	**
Expedite:	Yes • No	Date Se	nt: 09-Mar-2005	Due Back;
DP Ingredient:	000595, Hydrogen	peroxide		
DP Title:	· · · · · · · · · · · · · · · · · · ·	•		
CSF Included:	• Yes No	Label Induded: 🍎 Yes	No Pare	ent DP #:
Assigned To	<u>D</u>	Date in	Date Out	•
Organization: AD / P	SB	11-Mar-2005		Last Possible Science Due Oate: 16-Jun-2005
Team Name: EET		t1-Mar-2005	20-May-2005	Science Due Date: 25-May-2005
iewer Name: Whyte	, Nancy	11-Mar-2005	19-May-2005	Sub-Data Package Due Date: 11-May-2005
Contractor Name: DynCo	orp	t5-Mar-2005		
	*:	* * Studies Sent for R	eview * * *	
	* * * Addition	onal Data Package fo	r this Decis	ion * * *

Resubmitted additional efficacy studies for review; MRID Nos. 46480501, 46480502, 46480503, 46480504, 46480505; label and CSF included with this data package.

Action Code 188, Admin Due Date 95/25/95, EET Due Date 95/25/95, FQPA

\* \* \* Data Package Instructions \* \* \*

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itel classifor f.	rism have acceptable data for effectiveness as disinfectant. Data to support coli unacceptable due to tack of neutralizer testing data. Aspergillus data if dibution of 1:128 is used. Label needs minor currections.	
()Data Package	Comments   Waiver Documentation   Comment	
Service and an experience of the service of the ser	Sent From   열DP Dates   (출'MRIDS   변설Sub-DP   凸 DP Ingredients   [[[]DP Contract	答 Receipts
	16460504, 46460505, label and CSF included with this date package. Action Code 188, Admin Due Date 06/25/05, EET Due Date 05/25/05, FGPA	
Instructions;	Resubmitted additional efficacy studies for review; MRID Nos. 46480501, 46480502, 46480503.	
Bean Count.	1 Data Package Title:  Data Package Type:	Bear Sheet
DP Sequence:		Union Data Pig



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 2, 2005

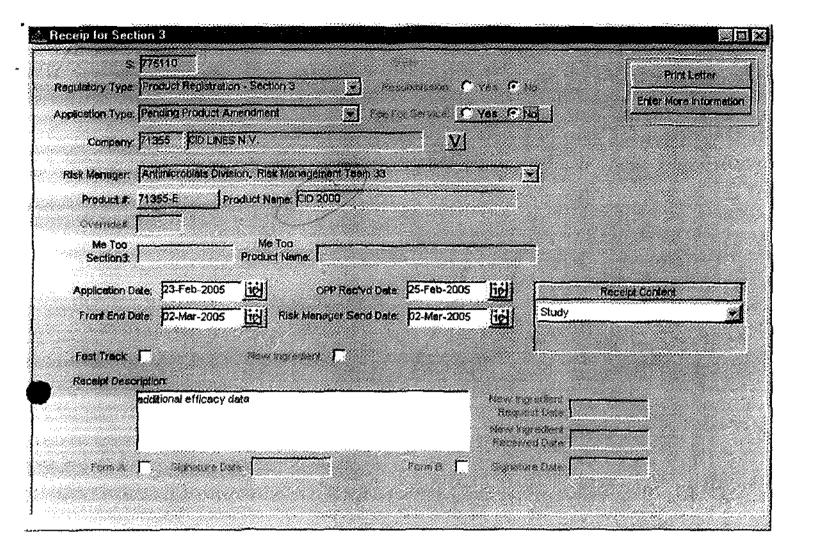
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

CID LINES N.V. SHENSTONE EST. 17804 BRAEMAR PL LEESBURG, VA 21076-7046

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 25-FEB-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



# Laird's Regulatory Consultants, Inc

Over 32 years Experience and Expertise in The Regulation of Pesticide Products

464805-00

February 22, 2005

Mr. Marshall Swindell, PM 33
Environmental Protection Agency
Regulatory Management I
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: CID 2000

EPA FILE SYMBOL 71355-E Your letter dated January 13, 2005

Dear Mr. Swindell:

Please find attached hereto, per my conversation with Ms. Leavy-Munk, concerning the product name change from CID 2000 KICKSTART. This is being done in an attempt to eliminate further questions or concerns about the name of the product as it is associated with the date being submitted.

The original application was submitted under the name of CID 2000 but during the process the company decided that they want the name KICKSTART so all data belongs to the same product. So I would like to request that the name be officially changed to KICKSTART as a part of the records for this registration.

Also attached hereto is 5 volumes of efficacy data to address the data requirements specified in the letter referenced above.

Should you have questions or concerns please don't hesitate to let me know.

Sincerely,

Olivia D. Laird

President/Owner/Agent

# TRANSMITTAL DOCUMENT

### 1. Name and Address of Submitter and Sponsor

#### SUBMITTER

Laird's Regulatory Consultants, Inc. 17804 Braemar Place Leesburg, VA 20175

#### **SPONSOR**

Mr. Vincent Catry NV Cid Lines Waterpoortstaat 2 8900 Ieper Belgium

## 2. Regulatory Action to Be Taken

Resubmission	of	additional	efficacy	data	to sur	port	claims
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EPA File Symbol/ Reg. No.: 71355-E
Product Name: KICKSTART old name CID 2000

#### Transmittal Date

February 23, 2005

## 3. List of Submitted Studies

Volume 1: Administrative Materials

46480601 Volume 2: Efficacy Data- AOAC Use Dilution Method, Fungicidal Modification

48480502 Volume 3: Efficacy Data-Virucidal Effectiveness (Marek's disease virus)

48480503 Volume 4: Efficacy Data-Virucidal Efficacy Test (Aspergillus Fumigatus)

48480504 Volume 5: Efficacy Data-Virucidal Evaluation of KICKSTART AGAINST

Avian Reovirus in a suspension Assay

46480505 Volume 6: Efficacy Data-Virucidal Evaluation of KICKSTART for use on

Inanimate Environmental Surfaces against Newcastle Disease Virus

Company Official: Jaura for Vincent Catry

Olivia D. Laird

Company Contact: Olivia D. Laird

Phone: (703) 669-0509 Fax: (703) 669-4608

VOLUME I OF 6

# **Summary Information For** Study 45767001

MRID: 45767001

Citation Reference: Bowdon, H. (2002) Virucidal Evaluation of Kick-Start For Use on Inanimate

Environmental Surfaces: Test for Efficacy Against Infectious Bursal Disease Virus: Lab Project Number: 01-7: 35. Unpublished study prepared by Southern Microbiology

Associates, LLC, 11 p.

Author: Bowdon, H.

**Content Category:** Complete primary report - experimental research

Receipt Date: 01-OcI-2002

Laboratory Project #: 01/7

Accession #: 457670 01

**Products Tested:** 

Status:

DP #:

## Ingredients

PC Code	CAS#	Ingredient Name
000595	7722-84-1	Hydrogen peroxide
Total Row	s: 1	

## Laboratory

Laboratory #	Laboratory Name
71355	CID LINES N.V.
954232	Southern Microbiology Associates, LLC
Total Rows: 2	

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Last updated on February 4, 2004, Version 1.4 http://dcoppbod01:7777/pls/oppina9p

# Results

# 4 Items Found

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	2)	45767002						
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	4)	46364201						
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# U.S. Environmental Protection Agency Office of Pesticide Programs Information Network

Study Query Result Page 1 of 1



DETAILS

Summary

Key Line

**Products Supported** 

Submitters

Laboratories

Study Details

Related MRIOs

**Back to Query** 

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Bibliography - Guideline

Bibliography - MRID

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### CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE
PEROXYACETIC ACID
Inert ingredients

4.9% 68.6 % 100.0%

26.5%

# KEEP OUT OF REACH OF CHILDREN

#### DANGER

Kickstart is effective against:

Bacteria:	dilution
Staphylococcus aureus (ATCC 6538)	1:256
Escherichia coli (ATCC 11229)	1:256
Listeria monocytogenes (ATCC 15313)	1:512
Mycoplasma gallinarum (ATCC 19708)	1:512
Salmonella Chloreasuis serotype enteritidis (ATCC 13076) NO	1:512
Pseudomonas Aeruginosa (ATCC 15442)	1:200
Fungus (on environmental surfaces):	
Aspergillus fumigatis (ATCC 36607)	1:128
Virus (on environmental surfaces):	
Infectious Bursal Disease of Chickens (ATCC D78,VR-2041)	1:384
Newcastle Disease (Spafas strain 539016)	1:384
Avian Reovirus (MERIAL SELECT strain 2408)	1:384
Marek's Disease virus (Spafas strain)	1:384
	Staphylococcus aureus (ATCC 6538)  Escherichia coli (ATCC 11229)  Listeria monocytogenes (ATCC 15313)  Mycoplasma gallinarum (ATCC 19708)  Salmonella Chloreasuis serotype enteritidis (ATCC 13076) NO  Pseudomonas Aeruginosa (ATCC 15442)  Fungus (on environmental surfaces):  Aspergillus fumigatis (ATCC 36607)  Virus (on environmental surfaces):  Infectious Bursal Disease of Chickens (ATCC D78,VR-2041)  Newcastle Disease (Spafas strain 539016)  Avian Reovirus (MERIAL SELECT strain 2408)

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	Call a poison control center or doctor for treatment advice.
IF ON SKIN or	Take off contaminated clothing
CLOTHING	<ul> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
	Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> </ul>
	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
	NOTE TO PHYSICIAN :
Prob	pable mucosal damage may contraindicate the use of gastric lavage

EPA Reg. N\*: 71355-EPA Est. N\*: 71355-BEL-001 NET CONTENTS: 1 - 5 gallon(s)

BATCH N\*: EXPIRY DATE:



#### APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment :

- 1. Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings).
- 2. Halchers, Setters, and chick processing facilities
- 3. Food processing plants (slaughterhouses)
- 4. Trucks and other vehicles

#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin, Harmful If swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with tabel directions prior to use. Kickstart is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Stale Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steet, copper, atuminum, finished wood, vinyl, plastics, glazed tiles, brick walls, sandwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all fitter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, Iroughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfecting solution should be made daily.



Produced by:
CID LINES NV/SA
Waterpoortstraat 2 - 8 8900 IEPER
BELGIUM - EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879
www.cidlines.com - Info@cidlines.com

#### 2. Hatcheries:

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or it visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect thard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles :

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Nover return Kickstart to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition, in case of decomposition, isotate container, douse container with cool water and dilute. Kickstatir with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Controt Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. Kickstart, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinee, Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is Intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrangs and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of texticity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warrings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in lort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed, in no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.



**CID 2000** 

CONGENTRATED BROAD SPECTRUM DISINFECTAN

Active Ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients

26.5% 4.9% 68.6 % 100.0%

# KEEP OUT OF REACH OF CHILDREN DANGER

CID 2000 is effective against :

Bacteria :	ditution
Staphylococcus aureus (ATCC 6538)	1:256
Escherichia coli (ATCC 11229)	1:256
Listeria monocytogenes (ATCC 15313)	1:512
Mycoplasma gallinarum (ATCC 19708)	1:512
Salmonella Chloreasuis serotype enteritidis (ATCC 13076)	1:512
Pseudomonas Aeruginosa (ATCC 15442)	1:200
Fungus (on environmental surfaces):	- "
Aspergillus fumigatis (ATCC 36607)	1:128
Virus (on environmental surfaces) :	~
Infectious Bursat Disease of Chickens (ATCC D78,VR-2041)	1:384
Newcastle Disease (Spalas strain 539016)	1:384
Avian Reovirus (MERIAL SELECT strain 2408)	1:384
Marek's Disease virus (Spalas strain)	1:384

All tests in the presence of 400ppm AOAC hard water and 5% organic load.

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN or	Take off contaminated clothing
CLOTHING	<ul> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
1	Call a poison control center or doctor for treatment advice.
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	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
	NOTE TO PHYSICIAN:
Prot	pable mucosal damage may contraindicate the use of gastric lavage

EPA Reg. N° : 71355-EPA Est. N° : 71355-BEL-001

NET CONTENTS: 1 - 5 gatton(s)

BATCH N°: EXPIRY DATE:



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8ELGIUM - EUROPE
Phone : 011 32 57 217877
Fax : 011 32 57 217879

www.critines.com - info@cidlines.com

#### APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

- Farm Equipment and animal housing buildings (poultry & lurkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings)
- 2. Halchers, Setters, and chick processing facilities
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- 4. Trucks and other vehicles.

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Hazard to Humans and Domestic Animals

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#### PHYSICAL AND CHEMICAL HAZARDS

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#### **DIRECTIONS FOR USE:**

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For disinfection of hard, non-porous surfaces : staintess, gatvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed files, brick walls, sandwich panels and feeding/drinking equipment :

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of bams, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing titler and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfecting solution should be made daily.



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BELGIUM - EUROPE
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#### 2. Hatcheries :

Hatcheries: Remove all animals from the area. Thoroughty clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animats or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly soiled.

#### 3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return CID 2000 to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shell life and can induce decomposition, in case of decomposition, isotate container, douse container with coof water and dilute CID 2000 with large volumes of water. Avoid damage to containers, Keep container closed at all times when not in use, Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden patlets.

Procedures for teak of spill: Stop teak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undituted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are acutely hazardous, Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law, it these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material tras been spilled, an acceptable method of disposal is to dilute with at teast 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposat of container: Tripte rose. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning, if burned, stay out of smoke.

Note: This product at its use dilution is compatible with staintess steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this labet are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor Intends, nor does it authorize any agent or representative to make, any other warrantles, expressed or implied, and it expressly excludes and disclaims all implied warrantles or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the /abet directions, warrings or cautions. Buyer's exclusive remedy and manufacturer's or setter's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.



Produced by:
CID LINES NV/SA
Waterpoortstreat 2 – B 8900 IEPER
BELGIUM – EUROPE
Ptione: 011 32 57 217877
Fax: 011 32 57 217879

www.cielines.com - info@cidlines.com

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



# OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES Antimicrobials Division

May 19, 2005

**MEMORANDUM:** 

EPA Reg. No 71355-E Kickstart (formerly CID 2000)

DP 314158

From:

Nancy Whyte, Efficacy Team Leader (Acting)

Efficacy Evaluation Team Product Science Branch

Antimicrobials Division (7510C)

To:

Marshall Swindell/Karen Leavy-Munk

Team 33, RMB I

Thru:

Michele E. Wingfield, Chief

Product Science Branch

Antimicrobials Division (7510C)

Registrant:

CID Lines NV/SSA

Waterpoorstaat 2-B 8900

leper, Belgium

Formulation Label:

% by wt.

Active Ingredient(s)

Total 100.0%

#### I. Background:

The product, *Kickslart* (EPA File Symbol 71355-E), is a new product. The applicant has submitted an application to register the product as a disinfectant (bactericide, fungicide, virucide) for use on hard, non-porous surfaces in commercial and animal care environments. The data package contains efficacy data submitted by the applicant to address requirements specified in an EPA letter, dated January 13, 2005. [A copy of this EPA letter was not included in the data package.] The label claims that the product is effective in the presence of 400 ppm hard water and a 5% organic soil load. Studies were conducted at MicroBioTest, Inc., located at 105B Carpenter Drive in Sterling, VA 20164; Southern Microbiology Associates, LLC, located

at 4204 Edmonton Dr., Bessemer, AL, 35022; and Hill Top Research, Inc., located at Main & Mill Streets, Miamiville, OH 45147.

This data package contained a letter from the applicant's representative to EPA (dated February 22, 2005), EPA Form 8570-4 (Confidential Statement of Formula), five studies (MRID Nos. 464805-01 through 464805-05), Statements of No Data Confidentiality Claims for all five studies, and the proposed label. This submission contained efficacy data which was requested by the Agency in 2004 as part of a Data Call-in (DCI) for the re-registration of products which contain mineral acids as an active ingredient. This product also contains iodine as an active ingredient. The efficacy data submitted was collected in 1981, and is not applicable at this time for re-registration. Since the submission of the efficacy data, the product registration has been cancelled.

#### II. Use Directions:

The product is designed to be used for disinfecting hard, non-food, non-porous surfaces such as animal housing facilities and equipment, trucks and vehicles, glazed tiles, sandwich panels, and feeding/drinking equipment. The product may be used on hard surfaces made of aluminum, copper, steel (i.e., stainless, galvanized, painted), finished wood, vinyl, and plastics. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare use solution by mixing an appropriate amount of the product with water (1:128 to treat against *Aspergillus fumigatis*; 1:256 to treat against *Escherichia coli*; and 1:384 to treat against viruses). Thoroughly clean all surfaces with soap or detergent. Rinse with water. Saturate all surfaces with the use solution by using a spray, mop, or sponge, or by immersion. Surfaces must remain wet for 10 minutes. Scrub feeding and water appliances with soap/detergent and rinse with potable water before reuse.

#### III Agency Standards for the Proposed Change:

Disinfectants for Use on Hard Surfaces (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10<sup>4</sup> microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 product samples representing 2 different product lots using the AOAC Fungicidal Test. The highest dilution that kills all fungal spores is the minimum effective concentration. These Agency standards are presented in DIS/TSS-6.

Alternatively, the AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. If the product is intended to be used as a spray product, the AOAC Germicidal Spray Products as Disinfectants Method must be

employed. The inoculum in the test must be modified to provide a concentration of at least 10<sup>6</sup> conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required. These Agency standards are also presented in DIS/TSS-6.

#### Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10<sup>4</sup> from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

#### Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

#### IV Comments on the Submitted Studies:

1. MRID 464805-01 "AOAC Use-Dilution Method Fungicidal Modification" for *Kickstart*, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – November 1, 2002. Laboratory Project No. 02-120838-106.

This study was conducted against *Aspergillus fumigatis* (ATCC 10894) and *Escherichia coli* (ATCC 11229). Two lots (Lot Nos. 201960 and 202760) of the product, *Kickstart*, were tested using the AOAC Use-Dilution Method (modified for fungi) or the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15<sup>th</sup> Edition, 1990 and in the AOAC International Official Methods of Analysis, 17<sup>th</sup> Edition, 2000. Horse serum was added to the culture to achieve a 5% organic soil load. A 1:256 use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in the suspensions of the test organisms. The carriers were dried for 40 minutes at 37±1°C. Each carrier was exposed to the use solution for 10 minutes at 20±1°C. Carriers contaminated with *Aspergillus fumigatis* were transferred to tubes of Potato Dextrose Broth with 25 mL/L AOAC Stock Neutralizer to neutralize. Tubes

containing Letheen Broth were used to neutralize carriers contaminated with *Escherichia coli*. Secondary subcultures were transferred 30 minutes after the primary subcultures. All *Aspergillus fumigatis* subcultures were incubated for 8 days at 25±1°C. *Escherichia coli* subcultures were incubated for 49.5 hours at 25±1°C. The subcultures were examined for the presence or absence of visible growth. Controls included those for viability and dried carrier count. According to the laboratory report, neutralizer effectiveness testing was conducted under a study assigned Hill Top Research Study No. 01-109138-106.

2. MRID 464805-02 "Virucidal Effectiveness Test, Marek's disease virus" for *Kickstart*, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – May 30, 2003. Laboratory Project Identification Number 431-111.

This study was conducted against Marek's disease virus (Strain not specified; obtained from Charles River Laboratories, SPAFAS), using primary chicken embryo fibroblasts (originally obtained from Charles River Laboratories, SPAFAS) as the host system. Two lots (Lot Nos. 300960 and 301160) of the product, Kickstart, were tested according to a MicroBioTest Protocol titled "Virucidal Effectiveness Test, Marek's disease virus," dated February 19, 2003 (copy provided). The stock virus culture contained at least a 5% organic soil load. A 1;384 use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at room temperature for 30 minutes. For each lot of product, separate dried virus films were treated with 2.0 mL of the use solution. The virus films were completely covered with the use solution. and remained exposed to the product for 10 minutes at 20±2°C. After exposure, the plates were neutralized with 2.0 mL of fetal bovine serum supplemented with 0.1% sodium thiosulfate and 0.0001% Catalase, and the mixture was scraped from the surface of the dish with a cell scraper. Each sample (0.5 mL) was loaded onto pre-spun Sephacryl columns and spun to obtain the eluate. Ten-fold serial dilutions were prepared, using Basal medium eagles supplemented with 5% calf serum. Primary chicken embryo fibroblasts in multi-well culture dishes were inoculated in quadruplicate with an unspecified amount of the dilutions. The cultures were incubated at 37±2°C in 5±1% CO<sub>2</sub> for 60-90 minutes for viral adsorption. Postadsorption, the media was aspirated, the monolayer was washed once with culture medium, and the cells were re-incubated at 37±2°C in 5±1% CO2 for 8-10 days. Post-incubation, the cultures were fixed with TC grade alcohol, stained, and scored for the presence or absence of unspecified cytopathic effects. Controls included those for cell viability/sterility, plate recovery, column titer, viral stock titer, cytotoxicity, and neutralizer effectiveness. The 50% fluorescent focus forming unit dose per mL (FFFUD<sub>sn</sub>) was determined using the method of Reed and Muench.

**Note:** Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 464805-03 "AOAC Fungicidal Effectiveness Test, Aspergillus fumigatis" for Kickstart, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – June 6, 2003. Laboratory Project Identification Number 431-109.

This study was conducted against *Aspergillus fumigatis* (ATCC 36607). Two lots (Lot Nos. 301160 and 300960) of the product, *Kickstart*, were tested using the AOAC Fungicidal Effectiveness Test as described in the AOAC Official Methods of Analysis, 16<sup>th</sup> Edition, 1995. Heat-inactivated fetal bovine serum was added to the culture to achieve a 5% organic soil load.

A 1:128 use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Ten (10) tubes containing 5 mL of the use solution were inoculated with 0.5 mL of the standardized inoculum of the test organism. After 10 minutes at 20±2°C, a sample of conidia-disinfectant from each tube was transferred with a 4-mm loop and placed in 10 mL of Neopeptone Glucose Broth with 0.05% thioglycolic acid and catalase to neutralize. A secondary transfer was made from each tube to a fresh tube of 10 mL of Neopeptone Glucose Broth. All subcultures were incubated for at least 10 days at 20-30°C. The subcultures were examined for the presence or absence of visible growth. Controls included those for viability, inoculum counts, sterility, initial counts, fungistasis, and confirmation of the challenge microorganism.

**Note:** Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

4. MRID 464805-04 "Virucidal Evaluation of *Kickstart* Against Avian Reovirus in a Suspension Assay," by Hazel R. Bowden. Study conducted at Southern Microbiology Associates, LLC. Study completion date – November 13, 2002. Laboratory Project Identification #01-7, Biocidal Test #59.

This study was conducted against Avian Reovirus (Strain 2408; obtained from MERIAL SELECT), using embryonated chicken egg cells as the host system. Two lots (Lot Nos. 104760 and 200260) of the product, Kick-Start, were tested using ASTM Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension. A 1:384 use solution of the product was prepared by adding 0.1 mL of the product to 38.3 mL of 400 ppm synthetic hard water (titrated at 392.3 ppm). The stock virus culture contained a 5% organic soil load (calf serum). Test tubes containing 5 mL of the use solution were inoculated with 0.1 mL of the virus in medium. The virus remained exposed to the use solution for 10 minutes at 23°C and a relative humidity of 61%. After exposure, serial dilutions were prepared immediately in Minimum Essential Medium supplemented with 2% fetal bovine serum. The rapid dilutions served as neutralization by dilution. Embryonated eggs were inoculated into the yolk sac in quadruplicate with 0.2 mL of the dilutions. Two days post-inoculation, all eggs were candled and dead embryos were discarded. The eggs were incubated for a total of 7 days at ~37°C in at ≥50% humidity. Controls included those for toxicity, virus titer, and neutralization. Viral and cytotoxicity titers were calculated by the method of Reed and Muench.

5. MRID 464805-05 "Virucidal Evaluation of *Kickstart* for Use on Inanimate Environmental Surfaces: Test for Efficacy against Newcastle Disease Virus," by Hazel R. Bowden. Study conducted at Southern Microbiology Associates, LLC. Study completion date – November 13, 2002. Laboratory Project Identification #01-7, Biocidal Test #54.

This study was conducted against Newcastle disease virus (Strain LaSota; obtained from Charles River Laboratories, SPAFAS), using chicken embryos as the host system. Two lots (Lot Nos. 104760 and 200260) of the product, Kick-Start, were tested. The product was diluted 1:384 by adding 0.1 mL of the product to 38.3 mL of 400 ppm synthetic hard water (titrated at 397 ppm). The virus culture was used at sufficient dilution to achieve a concentration of 5% allantoic fluid as the 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at 24°C and 68% relative humidity for 35-45 minutes. For each lot of product, separate dried virus films were treated with 2.0 mL of the use solution. The virus films were exposed to the use solution for 10 minutes at 24°C. The 10-minute exposure time included the 30 second filtration through the Sephadex column. The filtered virus-

disinfectant mixture was diluted serially in Minimal Essential Medium supplemented with 2% fetal bovine serum. The chorio-allantoic sacs of 9-day old chicken embryos were inoculated in quadruplicate with 0.2 mL of the dilutions and then re-incubated at ~37°C and ≥50% humidity for 8 days. Controls included those for toxicity, virus titer, and neutralization. Viral and cytotoxicity titers were calculated by the method of Reed and Muench.

#### V. Results:

MRID Number	Organism		No. Exhibiting Growth/ Total No. Tested			
	Lot No. 2019		Lot No. 202760	carrier)		
464805-01	Escherichia coli	1° 0/10 2° 0/10	1° 0/10 2° 0/10	1,3 x 10 <sup>7</sup>		

MRID Number	Organism	No. Exhibit Total No	Viability	
		Lot No. 201960	Lot No. 202760	
464805-01	Aspergillus fumigatus (ATCC 10894)	1° 10/10 2° 10/10	1° 10/10 2° 10/10	1.9 x 10⁵ conidia/carrier
		Lot No. 301160	Lot No. 300960	
464805-03	Aspergillus fumigatus (ATCC 36607)	1° 0/10 2° 0/10	1° 0/10 2° 0/10	9.0 x 10⁵ CFU/mL

MRID	Organism		Dried Virus			
Number			Lot No. 300960	1		
464805-02	Marek's disease virus	10 <sup>-2</sup> to 1 <b>0</b> <sup>-7</sup> dilutions	Complete inactivation	Complete inactivation	FFFUD <sub>50</sub> /mL 10 <sup>4,67</sup>	
		FFFUD <sub>50</sub> /mL	s 10 <sup>1.5</sup>	≤10¹⁵		
			Lot No. 104760	Lot No. 200260		
464805-04	Avian Reovirus	10 <sup>-1</sup> to 10 <sup>-6</sup> dilutions	Complete inactivation	Complete inactivation	TCID <sub>50</sub> /0.2 mL 10 <sup>5.0</sup>	
		TCID <sub>50</sub> /0.2 mL	0.2 mL ≤10°.5 ≤10°.5			
<b>46480</b> 5-05	Newcastle disease virus	10 <sup>-1</sup> to 10 <sup>-4</sup> dilutions	Complete inactivation	Complete inactivation	TCID <sub>50</sub> /0.2 mL 10 <sup>4.3</sup>	
		TCID <sub>50</sub> /0.2 mL	≤ 10 <sup>0,5</sup>	≤ 10° <sup>5</sup>		

#### Vi. Conclusions:

- 1. The submitted efficacy data (MRID No. 464805-01) do not currently support the use of the product, *Kickstart*, as a disinfectant with bactericidal activity against *Escherichia coli* on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (horse serum) for a contact time of 10 minutes at a 1:256 dilution. No growth was observed in the subcultures of the carriers tested against two lots of the product; however, the results of neutralizer effectiveness testing were not reported. Dried carrier counts were at least 10<sup>4</sup>. Viability controls were positive for growth. Purity controls were not reported. Sterility controls were not reported. The applicant needs to provide the results of neutralizer effectiveness testing, which was apparently conducted under a study assigned Hill Top Research Study No. 01-109138-106.
- 2. The submitted efficacy data (MRID No. 464805-01) do not support the use of the product, *Kickstart*, as a fungicide against *Aspergillus fumigatis* (ATCC 10894) on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (horse serum) for a contact time of 10 minutes at a 1:256 dilution. Growth was observed in all of the subcultures of the carriers tested against two lots of the product. [Note: The proposed label does not claim effectiveness against this fungus.]
- 3. The submitted efficacy data (MRID No. 464805-03) support the use of the product, Kickstart, as a disinfectant with fungicidal activity against Aspergillus fumigatis (ATCC 36607) on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (heat-inactivated fetal bovine serum) for a contact time of 10 minutes at a 1:128 dilution. No growth was observed when the product was tested against two lots of the product. Viability controls were positive for growth. Sterility controls did not show growth. Fungistatic streaks exhibited no growth.

4. The submitted efficacy data support the use of the product, Kickstart, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:384 dilution:

Avian Reovirus MRID No. 464805-04
Marek's disease virus MRID No. 464805-02
Newcastle disease virus MRID No. 464805-05

Complete inactivation (no growth) was indicated in all dilutions tested. Cytotoxicity was not observed. Recoverable virus titers of at least 10<sup>4</sup> were achieved.

#### VII. Recommendations:

- The proposed label claims that the product, Kickstart, is an effective disinfectant against Escherichia coli on hard, non-porous surfaces when used at a 1:256 dilution in the presence of 400 ppm hard water and a 5% organic load for a contact time of 10 minutes. Data provided by the applicant do not currently support this claim. As discussed in the Conclusions Section of this report, the applicant needs to provide the results of neutralizer effectiveness testing.
- The proposed label claims that the product, Kickstart, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic load for a contact time of 10 minutes when used at the dilutions specified:

Aspergillus fumigatis (ATCC 36607) 1:128 dilution Avian Reovirus (MERIAL SELECT strain 2408) 1:384 dilution Marek's disease virus (Spafas strain) 1:384 dilution Newcastle disease virus (Spafas strain) 1:384 dilution

Data provided by the applicant support these claims.

 The proposed label also includes claims of effectiveness against the following microorganisms:

Staphylococcus aureus (ATCC 6538)

Listeria monocytogenes (ATCC 15313)

Mycoplasma gallinarum (ATCC 19708)

Salmonella choleraesuis serotype enteritidis (ATCC 13076)

Pseudomonas aeruginosa (ATCC 15442)

Infectious Bursal Disease of Chickens (ATCC D78, VR-2041)

This data package did not include efficacy data to support these claims, nor was a data matrix which listed these organisms with the citations for MRIDs included in the current data package. It has been determined by additional review of previous submissions (DP 286206, dated January 22, 2003 and DP 308939, dated December 7, 2004) that efficacy testing has been conducted and is acceptable for all the organisms listed above.

5. In the future, the registrant or its representative must include a data matrix listing all organisms previously accepted by the Agency and listed on the proposed label.

- 6. The applicant must make the following changes to the proposed label, as appropriate:
  - On page 1, change "Salmonella Chloreasuis" to read "Salmonella choleraesuis".
  - On page 3, change "Procedures for leak of spill" to read "Procedures for leak or spill."
  - On page 3, change "regulatory agencies should be contacted by prior to disposal" to read "regulatory agencies should be contacted prior to disposal."
  - On page 3, change "Kickstart which is to discharged, should be disposed . . . ." to read "Dispose of *Kickstart* . . . . "

DP#. (314158)

Decision #: 216261

# DATA PACKAGE BEAN SHEET

Date: 10-Mar-2005
Page 1 of 2

# \* \* \* Registration Information \* \* \*

Registration:	71355-E - CID 2000			· · · · · · · · · · · · · · · · · · ·	
Company:	71355 - CID LINES	N.V.		** · · · · · · · · · · · · · · · · · ·	
Risk Manager:	RM 33 - Marshall Sv	vindell - (703) 308-6341 Room#	CM-2 308H		
Risk Manager <mark>Reviewe</mark> r:	Karen Leavy KLEA	VY	***************************************	Acceptance .	
Sent Date:	02-Mar-200 <del>5</del>	Calculated Due Dat	le: 25-Jun-2005	Edited Ope Date.	
Type of Registration	Product Registration	- Section 3			
Action Desc.	(188) ADDITIONAL	USE;NEW REGISTRATION;DL	O INGREDIENT;ME-	TDO:	
Ingredients:	000595, Hydrogen g	eroxide(20%)	····		
	*	* * Data Package In	formation * *	*	
Expedite.	💮 Yes 🌑 No	Date Ser	nt: 09-Mar-2005	Oue Back:	
DP Ingredient	000595, Hydrogen p	eroxide			
OP Title.			· · · · · · · · · · · · · · · · · · ·		
CSF Included	● Yes ( ) No	Label Included: • Yes			
Assigned To	0	Date In	Date Out		
Organization: AD / P	SB	The second secon	· 00 00—00 00— MARKATANATANATANATANATANATANATANATANATANATA	Administrative Due Date:	12-Jun-2005
Team Name: EET				Negotiated Due Date:	
eviewer Name:		entre and entre		Projected Completion Date:	
Contractor Name:					

# \* \* \* Studies Sent for Review \* \* \*

No Studies

# \* \* \* Additional Data Package for this Decision \* \* \*

Printed on Page 2

# \* \* \* Data Package Instructions \* \* \*

Resubmitted additional efficacy studies for review; MRID Nos. 46480501, 46480503, 46480504, 46480505, label and CSF included with this data package.

Action Code 188, Admin Due Date 06/25/05, EET Due Date 05/25/05, FQPA

# Laird's Regulatory Consultants, Inc

Over 32 years Experience and Expertise in The Regulation of Pesticide Products

February 22, 2005

464805-00

Mr. Marshall Swindell, PM 33 Environmental Protection Agency Regulatory Management I Antimicrobial Division (7510C) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

Subject: CID 2000

EPA FILE SYMBOL 71355-E Your letter dated January 13, 2005

Dear Mr. Swindell:

Please find attached hereto, per my conversation with Ms. Leavy-Munk, concerning the product name change from CID 2000 KICKSTART. This is being done in an attempt to eliminate further questions or concerns about the name of the product as it is associated with the date being submitted.

The original application was submitted under the name of CID 2000 but during the process the company decided that they want the name KICKSTART so all data belongs to the same product. So I would like to request that the name be officially changed to KICKSTART as a part of the records for this registration.

Also attached hereto is 5 volumes of efficacy data to address the data requirements specified in the letter referenced above.

Should you have questions or concerns please don't hesitate to let me know.

Sincerely,

Olivia D. Laird

President/Owner/Agent

## TRANSMITTAL DOCUMENT

## 1. Name and Address of Submitter and Sponsor

#### SUBMITTER

Laird's Regulatory Consultants, Inc. 17804 Braemar Place Leesburg, VA 20175

#### **SPONSOR**

Mr. Vincent Catry NV Cid Lines Waterpoortstaat 2 8900 Ieper Belgium

#### 2. Regulatory Action to Be Taken

	Resubmission	of	additional	efficacy	data	to	support	claims
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EPA File Symbol/ Reg. No.: 71355-E

Product Name: KICKSTART old name CID 2000

#### Transmittal Date

February 23, 2005

#### 3. List of Submitted Studies

Volume 1: Administrative Materials

46480601 Volume 2: Efficacy Data- AOAC Use Dilution Method, Fungicidal Modification

46480502 Volume 3: Efficacy Data-Virucidal Effectiveness (Marek's disease virus)

48480503 Volume 4: Efficacy Data-Virucidal Efficacy Test (Aspergillus Fumigatus)

46480504 Volume 5: Efficacy Data-Virucidal Evaluation of KICKSTART AGAINST

Avian Reovirus in a suspension Assay

46480505 Volume 6: Efficacy Data- Virucidal Evaluation of KICKSTART for use on

Inanimate Environmental Surfaces against Newcastle Disease Virus

Company Official: Little for Vincent Catry

Company Contact:

Olivia D. Laird

Phone: (703) 669-0509 Fax: (703) 669-4608

**VOLUME I OF 6** 

# **KICKSTART**

#### CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE 26.5%
PEROXYACETIC ACID 4.9%
Inert ingredients 68.6 %
100.0%

# KEEP OUT OF REACH OF CHILDREN

## **DANGER**

Kickstart is effective against:

Bacteria :	dilution
Staphylococcus aureus (ATCC 6538)	1:256
Escherichia coli (ATCC 11229)	1:256
Listeria monocytogenes (ATCC 15313)	1:512
Mycoplasma gallinarum (ATCC 19708)	1:512
Salmonella Chloreasuis serotype enteritidis (ATCC 13076)	1:512
Pseudomonas Aeruginosa (ATCC 15442)	1:200
Fungus (on environmental surfaces):	
Aşpergillus fumigatis (ATCC 36607)	1:128
Virus (on environmental surfaces) :	<u> </u>
Infectious Bursal Disease of Chickens (ATCC D78,VR-2041)	1:384
Newcastle Disease (Spafas strain 539016)	1:384
Avian Reovirus (MERIAL SELECT strain 2408)	1:384
Marek's Disease virus (Spafas strain)	1:384
191.7. 12	<del></del>

All tests in the presence of 400ppm AOAC hard water and 5% organic load.

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove conlact lenses, if present, after the first 5 minutes, then continue ninsing eye.</li> </ul>
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OF CLOTHING	<ul> <li>Take off contaminated clothing</li> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
	NOTE TO PHYSICIAN :
Prob	hable mucosal damage may contraindicate the use of gastric lavage

EPA Reg. N°: 71355-EPA Est. N°: 71355-BEL-001

! 1

NET CONTENTS: 1 - 5 gallon(s)

BATCH N\*: EXPIRY DATE:



Produced by:
CID LINES NV/SA
Waterpoortstraat 2 - 8 8900 IEPER
BELGIUM - EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879

#### 2. Hatcheries:

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly soiled.

## 3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return Kickstart to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute Mickstatt with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. Kickstart which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; [b] that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and [c] that the directions, warrings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of loxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be selely responsible for, any and all foss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed, in no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.



#### APPLICATION:

Disinfection of non-lood surfaces, farm, animal, and poultry housing facilities and equipment :

- 1. Farm Equipment and animal housing buildings (poultry & lurkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
- 2. Halchers, Setters, and chick processing facilities
- 3. Food processing plants (slaughforhouses)
- 4. Trucks and other vehicles

#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. **Kickstart** is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steet, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, brick walls, sandwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with polable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Atlow to air dry.
- F. Fresh disinfecting solution should be made daily.



Produced by:
CID LINES NV/SA
Waterpoortstraat 2 – 8 8900 IEPER
BELGIUM – EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879

# **KICKSTART**

# CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients

26.5% 4.9% 68.6 %

100.0%

# KEEP OUT OF REACH OF CHILDREN

#### DANGER

Kickstart is effective against:

Bacteria :	dilution
Staphylococcus aureus (ATCC 6538)	1:256
Escherichia coli (ATCC 11229)	1:256
Listeria monocytogenes (ATCC 15313)	1:512
Mycoplasma gallinarum (ATCC 19708)	1:512
Salmonella Chloreasuis serotype enteritidis (ATCC 13076)	1:512
Pseudomonas Aeruginosa (ATCC 15442)	1:200
Fungus (on environmental surfaces):	
Asporgillus fumigatis (ATCC 36607)	1:128
Virus (on environmental surfaces):	
Infectious Bursal Disease of Chickens (ATCC D78,VR-2041)	1:384
Newcastle Disease (Spafas strain 539016)	1:384
Avian Reovirus (MERIAL SELECT strain 2408)	1:384
Marek's Disease virus (Spafas strain)	1:384

All tests in the presence of 400ppm AOAC hard water and 5% organic load.

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN or CLOTHING	<ul> <li>Take off contaminated clothing</li> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
	Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> </ul>
	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	Do not give anything by mouth to an unconscious person.
	NOTE TO PHYSICIAN:
Pro	bable mucosal damage may contraindicate the use of gastric lavage

EPA Reg. N°: 71355-

EPA Est. Nº: 71355-BEL-001

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NET CONTENTS: 1 - 5 gallon(s)

BATCH N°: EXPIRY DATE:



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BELGIUM - EUROPE
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#### 2. Hatcheries:

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or it visibly soiled.

#### 3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return Kickstart to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute. Kickstatr with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

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#### **APPLICATION:**

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Disinfection of non-food surfaces, larm, animal, and poultry housing facilities and equipment :

- 1. Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3. Food processing plants (slaughterhouses)
- 4. Trucks and other vehicles

#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhated or absorbed through the skin. Harmful if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

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- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all titter and manure from floors, walts and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or entploy equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfecting solution should be made daily.



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Fax : 011 32 57 217879

www.cidlines.com - Info@cidlines.com

# **KICKSTART**

#### CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE 26.5% PEROXYACETIC ACID 4.9% Inert ingredients 68.6 % 100.0%

# KEEP OUT OF REACH OF CHILDREN

#### DANGER

Kickstart is effective against:

Bacteria :	dilution
Staphylococcus aureus (ATCC 6538)	1:256
Escherichia ∞li (ATCC 11229)	1:256
Listeria monocytogenes (ATCC 15313)	1:512
Mycoplasma gallinarum (ATCC 19708)	1:512
Salmonella Chloreasuis serotype enteritidis (ATCC 13076)	1:512
Pseudomonas Aeruginosa (ATCC 15442)	1:200
Fungus (on environmental surfaces):	
Aspergillus fumigatis (ATCC 36607)	1:128
Virus (on environmental surfaces) :	
Infectious Bursal Disease of Chickens (ATCC D78,VR-2041)	1:384
Newcastle Disease (Spafas strain 539016)	1:384
Avian Reovirus (MERIAL SELECT strain 2408)	1:384
Marek's Disease virus (Spafas strain)	1:384
All takes in the second of 400 and 400	

All tests in the presence of 400ppm AOAC hard water and 5% organic load.

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	Call a poison control center or doctor for treatment advice.
IF ON SKIN or CLOTHING	<ul> <li>Take off contaminated clothing</li> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
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IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
<u> </u>	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
	NOTE TO PHYSICIAN:
Prol	bable mucosal damage may contraindicate the use of gastric lavage.

EPA Reg. N°; 71355-

EPA Est. Nº: 71355-BEL-001

NET CONTENTS: 1 - 5 gallon(s)

BATCH N°:

EXPIRY DATE !



Produced by: CID LINES NV/SA Waterpoortstraat 2 – B 8900 IEPER BELGIUM – EUROPE Phone: 011 32 57 217877

#### 2. Hatcheries:

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly soited.

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Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles :

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

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#### APPLICATION:

Disinfection of non-food surfaces, farm, animat, and poultry housing facilities and equipment :

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- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
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- F. Fresh disinfecting solution should be made daily.



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# **KICKSTART**

# CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE 26.5%
PEROXYACETIC ACID 4.9%
Inert ingredients 68.6 %
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# KEEP OUT OF REACH OF CHILDREN

#### DANGER

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IF SWALLOWED	Call a poison control center or doctor immediately for treatment advice.
011/12/01/25	<ul> <li>Have person sip a glass of water if able to swallow</li> </ul>
1	<ul> <li>Do not induce vomiling unless told to do so by a poison control center or doctor.</li> </ul>
	Do not give anything by mouth to an unconscious person.
	NOTE TO PHYSICIAN:
Prob	able mucosal damage may contraindicate the use of gastric lavage

EPA Reg. Nº: 71355-

NET CONTENTS: 1 - 5 gallon(s)

BATCH N°: EXPIRY DATE:

EPA Est. Nº: 71355-BEL-001



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Before using this product, all food products and packaging materials must be removed from the room or carofully protected. Pre-clean surfaces if visibly soiled, Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return Kickstart to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute. Kickstatz with targe volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. Kickstart which is to discharged, should be disposed of as hazardous waste after contacting the appropriato local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a senitary landfill. Disposal by inclineration, or if allowed by state and local authorities, by burning, if burned, stay out of smoke.

Note: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this label are based upon responsible experts evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes not intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be safely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warrings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in toxi of otherwise, shall be limited, at the manufacturer's option, to reptacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed, in no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.



#### APPLICATION:

Disinfection of non-lood surfaces, farm, animal, and poultry housing facilities and equipment:

- 1. Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3. Food processing plants (slaughterhouses)
- 4. Trucks and other vehicles

### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. Kickstart is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters untess in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces: staintess, galvanized and painted steel, copper, atuminum, finished wood, vinyt, plastics, glazed tiles, brick walls, sandwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove at litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfecting solution should be made daily.



Produced by:
CID LINES NV/SA
Walerpoortstraal 2 – B 8900 IEPER
BELGIUM – EUROPE
Phone: 011 32 57 217877
Fax: 011 32 57 217879

www.cidlines.com - info@cidlines.com

Administrative

Materials

DP # (314159) Decision #: 352866

# **DATA PACKAGE BEAN SHEET**

Date: 09-Mar-2005 Page 1 of 1

# \* \* \* Registration Information \* \* \*

Registration:	2568-RNR - ANTIFOU	LING SEAVICTOR 50 D	ARK RED 3GBDRD	en e		
Company:	2568 - JOTUN PAINTS	S INC.		· was		
Rísk Manager:	RM 33 - Marshall Swindell - (703) 308-6341 Room# CM-2 308H					
Risk Manager Reviewer	Karen Leavy KLEAVY			ny and a		
Sent Date:	07-Mar-2005	Calculated Du	e Date:	Edited Due Date	Amaganian	
Type of Registration:	Product Registration - Section 3					
Action Desc:	(A54) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;					
Ingredients:	025601, Cuprous oxide	e( <b>3</b> 9.59%)				
		cotone, 4,5-dichtoro-2-oc				
	* *	* Data Packag	e Information * *	*		
Expedite:	🔾 Yes 🌑 No	Dat	le Sent: 09-Mar-2005	Due Back	Maranta Amerika (uran uran uran uran uran uran uran uran	
DP Ingredient:	025601, Cuprous oxide					
	128101, 3(2H)-Isothlazolone, 4,5-dichloro-2-octyl-					
DP Title:			·			
CSF Included:	● Yes ( No	Label Included: 🌘 '	Yes 🦳 No Parent l	DP #:		
Assigned To	<u>o</u>	Date in	Date Out			
Organization: AD / R	VASSB	***************************************	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Administrative Due Date:	05-Sep-2005	
Team Name: RASS			y sansanna a a anna a anna anna anna ann	Negotiated Due Date:		
Seviewer Name:				Projected Completion Date:		
contractor Name:			· · · · · · · · · · · · · · · · · · ·			

\* \* \* Studies Sent for Review \* \* \*

No Studies

\* \* \* Additional Data Package for this Decision \* \* \*

No Additional Data Packages

\* \* \* Data Package Instructions \* \* \*

Please review the submitted leach rate studies. Action code A54

DECISION PKG. F				
			IBR KLESNY-MLE	
CODING FORM F	FOR APPLICAT	IONS FOR REC	<u> </u>	MENDMENTS
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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

JAN I 8 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Olivia Laird Regulatory Agent for, c/o NV Cid Lines SA Laird's Regulatory Consultants, Inc. 501 South Lincoln Ave. Sterling, VA 20164-2024

Subject: CID 2000

EPA File Symbol 71355-E

Your Application Dated September 16<sup>th</sup>, 2004 EPA Received Date September 16<sup>th</sup>, 2004

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add efficacy claims to the proposed product labeling, is unacceptable.

### **EFFICACY**

The acceptable data for Salmonella cholcraesuis has not been submitted to the Agency for our review. Therefore, the product is not supported as a general, broad spectrum disinfectant.

However, the product has been found to be effective against both Pseudomonas aeruginosa and Staphylococcus aureus.

### LABELING

The proposed label claims that the product, CID 2000, is an effective disinfectant against Pseudomonas aeruginosa in the presence of 400 ppm AOAC hardwater and a 5% soil load at a dilution of 1:200 for a contact time of 10 minutes. These claims are acceptable and supported by submitted data.

The proposed label makes no claim for Salmonella cholcraesuis ATCC 10708. Adequate efficacy data must be submitted for this organism to maintain the broad spectrum disinfectant claim that appears on the labet. Until this data is submitted the use of the phrase "broad spectrum disinfectant" is unacceptable.

The proposed label claims that the product is efficacious against Escherichia coli ATCC 11229, at a dilution of 1:256 for a contact time of 10 minutes. This claim is unacceptable. Our letter of January 29th, 2003, explained that the submitted study for E. coli at a dilution of 1:512 failed as there was no growth on the 10 carriers. There is no record of a current submission that included new data for E. coli which meets the Agency requirements, or a study that was conducted at the label specified dilution. Resubmit data that supports the label claim for Escherichia coli at 1:256 dilution.

Aspergillus fumigatus is an organism of public health concern. The proposed label claims that the product is effective against this organism at a 1:128 concentration and a contact time of 10 minutes. This claim is unacceptable and must be removed from the product label unless efficacy data is submitted to support this claim.

Submit data to support the labeling claims for Salmonella choleraesuis, Escherichia coli, and Aspergillus fumigatus.

### OR

Delete all claims that reference the following organisms; Salmonella choleracsuis, Escherichia coh, and Aspergillus fumigatus from the proposed product labeling.

Resubmit corrected efficacy data for Salmonella choleraesuis to support the use of the product as a general, broad spectrum disinfectant.

A complete copy of the efficacy review is enclosed for your records.

The Agency reserves a full label review until the above discrepancies have been clarified.

The product may not be lawfully distributed in interstate commerce until the above discrepancies have been clarified.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)

# Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

September 16, 2004

Mr. Marshall Swindell, PM 33
Environmental Protection Agency
Regulatory Management
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Subject: CID 2000 (Kickstart)

**EPA FILE SYMBOL 71355-E** 

Resubmission of additional corrected data to support registration

Dear Mr. Swindell:

Attached hereto please find five (5) copies of the revised labeling containing our proposed uses. Also included with this package are the supportive corrected efficacy data which will address efficacy concerns for the product referenced.

Please note, the name Kickstart, as was explained in an earlier letter from the registrant contained on the efficacy data, is just one of the potential additional brand names for this product. Rest assured it is the same formula.

Thank you for your help in this matter. Should you have any questions or concerns please don't hesitate to let me know.

Sincerely,

President/Agent

# TRANSMITTAL DOCUMENT

## 1. Name and Address of Submitter and Sponsor

### SUBMITTER

Laird's Regulatory Consultants, Inc. 17804 Braemar Place Leesburg, VA 20175

### SPONSOR

Mr. Vincent Catry NV Cid Lines Waterpoortstaat 2 8900 Ieper Belgium

### 2. Regulatory Action to Be Taken

Resubmission of additional corrective data per Agency's Request

EPA File Symbol/Reg. No.: 71355-E

Product Name: Cid 2000/ Kickstart

### Transmittal Date

September 16, 2004

### 3. List of Submitted Studies

Volume 1: Administrative Materials

48364201 Volume 2: Efficacy Data (AOAC Use Dilution Test)

Company Official: for Vincent Catry

Company Contact: Olivia D. Laird

Phone: (703) 669-0509 Fax: (703) 669-4608

VOLÙME I

# **CID 2000**

### CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients

26.5% 4.9% 68.6 % 100.0%

### KEEP OUT OF REACH OF CHILDREN

### DANGER

	CID 2000 Is effective against :	
$\leq$ e $^{VJ^{\mu_{\nu}}}$	CID 2000 Is effective against :	1 211
VA.	Dacteria .	dilution
	Staphylococcus aureus (ATCC 6538)	1:256
	Escherichia coli (ATCC 11229) Not acceptible	1:256
	Listeria monocylogenes (ATCC 15313)	1:512
	Mycoplasma gallinarum (ATCC 19708)	1:512
i.	Salmonella (Chloreasuis) serotype enteritidis (ATCC 13076)	1:512
	Pseudomonas Aeruginosa (ATCC 15442)	1:200
	Fungus (on environmental surfaces) :	
	Aspergillus fumigatis (ATCC 36607) Funtion +US	1:128
	Virus (on environmental surfaces) :	2
	Infectious Bursal Disease of Chickens (ATCC D78, VR-2041)	1:384
	Newcastle Disease (Spafas strain 539016)	1:384
	Avian Reovirus (MERÍAL SELECT strain 2408)	1:384
	Marek's Disease virus (Spafas strain)	1:384

	FIRST AID STATEMENTS
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN or	Take off contaminated clothing
CLOTHING .	<ul> <li>Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li> </ul>
	Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow</li> </ul>
do pundo de secretario de la constante de la c	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
	NOTE TO PHYSICIAN :

Probable mucosal damage may contraindicate the use of gastric lavage

EPA Reg. Nº: 71355-EPA Est. Nº: 71355-BEL-001

The state of the s

NET CONTENTS: 1 - 5 gallon(s)

BATCH N°: EXPIRY DATE:



Produced by: CID LINES NVISA Waterpoortstrast 2 -- B 8900 IEPER BELGIUM - EUROPE Phone : 011 32 57 217877 Fax : 011 32 57 217879 www.cidlines.com - info@cidlines.com

### APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

- 1. Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3. Food processing plants (staughterhouses)
- 4. Trucks and other vehicles

### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

### PHYSICAL AND CHEMICAL HAZARDS

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. CID 2000 is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces; stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, brick walls, sandwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all titter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with scap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovets, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfecting solution should be made daily.



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BELGIUM – EUROPE
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www.cidlines.com - info@cidlines.com

### 2. Hatcheries :

Hatcheries: Remove alt animats from the area. Thoroughly clean alt surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate alt surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animats or emptoy equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

### 4. Trucks and other vehicles:

Clean att vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat att vehicles. Leave att treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return CID 2000 to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute CID 2000 with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off Ignition sources; no flames, smoking, flares or spark-producing toots. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to tabel instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse, Then offer for recycling or puncture and dispose in a satisfary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: This product at its use dilution is compatible with staintess steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

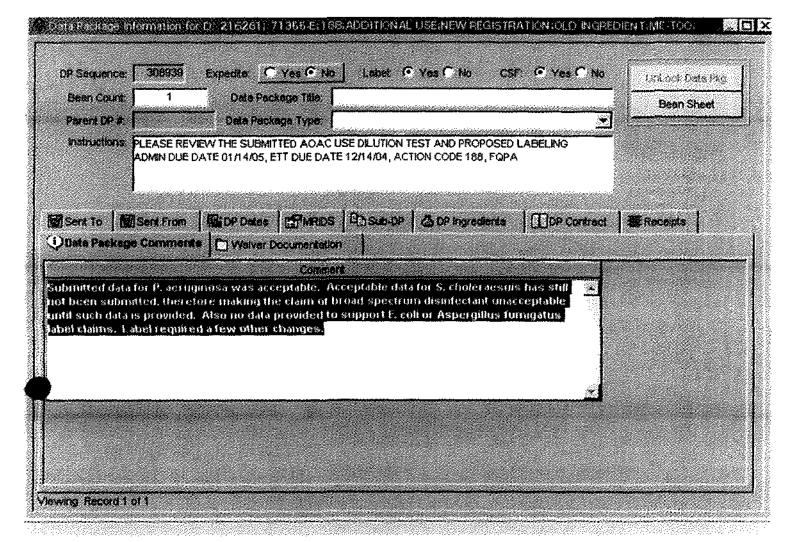
#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasunable tit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this tabet are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the tabel directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be table for special, indirect or consequential damages resulting from the use or handling of this product.



Produced by :
CID LINES NV/SA
Waterpoortstraat 2 – B 8900 IEPER
BELGIUM – EUROPE
Phone : 0 t1 32 57 217877
Fax : 0 t1 32 57 217879

www.cidlines.com - info@cidlines.com





Volume 2

# FINAL REPORT AOAC USE DILUTION TEST

Test Agent: Kickstart

<u>Data Requirements</u> EPA Guidelines 810.2100 (c), (d), (e)

> Author Felicia L. Sellers

Study Completion Date 05/30/03

Performing Laboratory MICROBIOTEST, INC. 105B Carpenter Drive Sterling, Virginia 20164

<u>Laboratory Project Identification Number</u>
431-107

Submitted to: NV CID LINES
Waterpoortstraat 2
Industnezone Isperieekanaal 8900
IEPER BELGIUM

Page 1 of 22



### STATEMENT OF NO DATA CONFIDENTIALITY

Title: AOAC Use Dilution Test

Performed by: MICROBIOTEST, INC.

105B Carpenter Drive Sterling, Virginia 20164

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B) or (C).

Company Agent





### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

### December 7, 2004

### <u>MEMORANDUM</u>

Efficacy Review for CID 2000, EPA Reg. No. 71355-E; Subject:

DP Barcode: D308939

Marcie Wawzysko, Microbiologist Marcie Dangero Product Science Branch 12/7/04 Antimicrobials Division (7510C) From:

Antimicrobials Division (7510C)

Nancy Whyte, Acting Team Leader
Product Science Branch
Antimicrobials Division (75100) Thru:

Antimicrobials Division (7510C)

Michele E. Wingfield, Chief Product Science Branch

Antimicrobials Division (7510C)

To: Marshall Swindell PM 33 / Karen Leavy

> Regulatory Management Branch I Antimicrobials Division (7510C)

Applicant: CID Lines N.V.

Waterpoortstraat 2

B 8900 leper, Belgium-Europe

### Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	26.5%
Peroxyacetic Acid	
Other ingredients.	
Total	

### I. BACKGROUND

The product, CID 2000 (EPA Reg. No. 71355-E), is a new product. The applicant has requested to register the product as a broad spectrum disinfectant (bactericide, virucide, fungicide) for use on hard, non-porous surfaces in farm, animal, and poultry housing facilities and equipment, food processing plants, and hatcheries. The label claims that the product is effective in the presence of 40ppm AOAC hard water and a 5% organic soil load. The applicant has resubmitted data for *Pseudomonas aeruginosa in* response to an Agency request. The submitted study was conducted at MicroBioTest Inc., located at 105B Carpenter Drive in Sterling, VA 20164.

The data package contained a letter from the applicant's representative to the Agency (dated September 16, 2004), Agency form 8570-4 (Confidential Statement of Formula), one study (MRID 463642-01) with Statements of No Data Confidentiality, Compliance, and Quality Assurance, and the proposed label (pin-punched September 16, 2004 by the Agency).

Note: Information in the data package indicates that Kickstart is an alternate reference name for the product, CID 2000.

### II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces on farm equipment, animal housing buildings, floors, walls, pens, stalls, chutes, cages, feeding/drinking equipment, handling/restraining equipment, vehicles, hatchers, setters, trays, racks, carts, tables, chick boxes, and animal cages. The product may be used on hard, non-porous surfaces such as steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, and sealed brick walls.

Directions on the proposed label provide the following information regarding preparation and use of the product as a disinfectant on farm equipment and animal housing buildings: Thoroughly clean surfaces with soap or detergent. Rinse with water. Saturate surfaces with disinfection solution using spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Rinse feeding and watering appliances with potable water before reuse.

The proposed label also includes directions for the disinfection of hatcheries, food processing plants, and trucks and other vehicles.

### III. AGENCY STANDARDS FOR PROPOSED CLAIMS

### Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested

with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis ATCC 10708 (for effectiveness against Gramnegative bacteria), Staphylococcus aureus ATCC 6538 (for effectiveness against Grampositive bacteria), and Pseudomonas aeruginosa ATCC 15442 (representative of a nosocomial pathogen). [180 carriers per sample; a total of 540 carriers] To pass performance requirements, tests must result in killing in 59 out of each set of 60 carriers to give a 95% confidence level. These agency standards can be found in DIS/TSS-1.

### Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10<sup>6</sup> /ml) of conidia. These agency standards can be found in DIS/TSS-2.

### IV. SUMMARY OF SUBMITTED STUDY

MRID 463642-01 "AOAC Use Dilution Test" for Kickstart by Felicia L. Sellers. Study conducted by MicroBio Test, Inc., Laboratory Project Number 431-107. Study completed May 30, 2004.

This study was conducted against *Pseudomonas aeruginosa* ATCC 15442. Three lots (Lot Nos. 301160, 300960, and 300260) of the product, Kickstart, were tested using the AOAC Use Dilution Test Method as described in AOAC Official Methods of Analysis, 16<sup>th</sup> Edition, 1995. At least one of the product lots (Lot No. 300260) was at least 60 days old at the time of testing. A 1:200 use solution of the product was prepared using 400 ppm AOAC hard water. Heat-inactivated horse serum was added to the inoculum to create a 5% organic soil load. Sterile stainless steel penicylinder carriers were inoculated with 48-54 hour old bacterial cultures at a ratio of 1mL inocula per carrier. Carriers remained in contact with the inoculum for 15 minutes at room temperature then dried for 25 minutes at 37±2°C. Contaminated carriers were exposed to 10 mL aliquots of the test agent for 10 minutes at 20±1°C then transferred to letheen broth containing 0.05% thioglycolic acid and catalase to neutralize. Subcultures were incubated for 48±2 hours at 37±2°C and examined for the presence or absence of visible growth. Study controls included those for sterility, neutralizer effectiveness, carrier counts, viability, bacteriostasis, and confirmation of the challenge microorganism.

### V. RESULTS

MRID	Organism	Results (Tube	Dried Corrier		
Number		Lot No. 301160	Lot No. 300260	Dried Carrier Count (Avg. CFU/Carrier)	
463642-01	Pseudomonas aeruginosa	0/60	0/60	0/60	2.1 x 10 <sup>5</sup>

### VI. CONCLUSIONS

The submitted efficacy data (MRID No. 463642-01) **support** the use of the product, CiD 2000, as a disinfectant with bactericidal activity against *Pseudomonas aeruginosa* on hard, non-porous surfaces for a contact time of 10 minutes at a dilution of 1:200 in the presence of hard water and a 5% organic load. No growth was seen on any of the carriers tested for the three product lots (one of which being at least 60 days old). The dried carrier count exceeded 10<sup>4</sup>. Study controls met the criteria for a valid test.

However, even though the product has been found to be effective against both Pseudomonas aeruginosa and Staphylococcus aureus, acceptable data for Salmonella choleraesuis has not been submitted. Thus the product is **not supporte**d for use as a general, broad spectrum disinfectant.

### VII. RECOMMENDATIONS

- 1. The proposed label claims that the product, CID 2000, is an effective disinfectant against *Pseudomonas aeruginosa* in the presence of 400 ppm AOAC hard water and a 5% soil load at a dilution of 1:200 for a contact time of 10 minutes. These claims are **acceptable** and supported by submitted data.
- 2. The proposed label makes no claim for Salmonella choleraesuis ATCC 10708. Adequate efficacy data must be submitted for this organism to maintain the broad spectrum disinfectant claim that appears on the label. Until this data is submitted the use of the phrase "broad spectrum disinfectant" is unacceptable.
- 3. The proposed label claims that the product is efficacious against Escherichia coli ATCC 11229, at a dilution of 1:256 for a contact time of 10 minutes. This claim is unacceptable. A January 29, 2003 letter to the applicant's representative explained that the submitted study for E.coli at a dilution of 1:512 failed as there was growth on the 10 carriers. There is no record of the applicant submitting new data for E.coli which meets Agency requirements, or a study that was conducted at the label specified

- dilution. The applicant must submit data to support the label claim for Escherichia coli at a 1:256 dilution.
- 4. Aspergillus fumigatus is an organism of public health concern. The proposed label claims that the product is effective against this organism at a 1:128 concentration and a contact time of 10 minutes. This claim is unacceptable and must be removed from the product label unless efficacy data is submitted to support this claim.
- 5. The following administrative changes need to be made to the proposed label:
  - a. On page 1, Salmonella choleraesuis serotype enteritidis is incorrectly spelled "Salmonella Cholereasuis serotype enteritidis." This must be corrected.
  - b. On page 1, Aspergillus fumigatus is incorrectly spelled "Aspergillus fumigatis." This must be corrected.
  - c. On page 2, brick walls are listed as a use surface. Brick is porous, this reference must be either removed from the label or altered to read "sealed brick walls."



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIOES AND TOXIC SUBSTANCES

July 16, 2003

### **MEMORANDUM:**

Subject: Efficacy Review for EPA Reg. No.: 71355-E, "CID 2000"

DP Barcode: D290087 Case No: 069188

From: Emily Mitchell, M.S., Team Leader

Efficacy Evaluation Team Product Science Branch

Antimicrobials Division (7510C)

To: Marshall Swindell PM33/Karen Leavy-Munk

Regulatory Management Branch I Antimicrobials Division (7510C)

Applicant: NV CID Lines SA

Waterpoortstraat 2 B 8900 leper

Belgium-Europe

### Formulation From Label:

Active Ingredient(s)	<u>% by wt.</u>
Hydrogen peroxide	26.5%
Peroxyacetic acid	4.9%
Inert Ingredient(s)	68.6%
Total	100.0%

### I BACKGROUND

The product, CID 2000 (EPA Reg. No. 71355-E), is a new product. The applicant requested to register the product as a broad spectrum disinfectant (bactericide, virucide) for use on hard, non-porous, non-food contact surfaces on farms and in veterinary hospitals and food processing plants. The label claims that the product is effective in the presence of "400 ppm AOAC synthetic hard water with 5% soil load." This data package is a re-submission of information in response to an EPA letter dated January 29, 2003. In its letter, EPA notified the applicant's representative that the submitted efficacy data did not support the use of the product against Salmonella choleraesuis. EPA requested clarification of whether 10 or 60 carriers were tested in the study against Salmonella choleraesuis. In addition, EPA requested additional data demonstrating effectiveness of the neutralizer against Salmonella choleraesuis if 60 carriers were tested. The applicant submitted amended efficacy data for the study against Salmonella choleraesuis. The study was conducted at Hill Top Research, Inc., located on Main and Mill Streets, Miamiville, OH 45147.

This data package contained a copy of an EPA letter to the applicant's representative (dated January 29, 2003), EPA Form 8570-4 (Confidential Statement of Formula), one study (MRID No. 459188-01), Statements of No Data Confidentiality Claim for the study, and the proposed label (pin-punched 10/1/02, by EPA).

Note: The data package also included a label for the acid-based sanitizer, CID 2000 (pin-punched 9/12/00, by EPA). The label for the acid-based sanitizer, CID 2000, appears to be irrelevant to the data package and may be a previous draft of the product label.

Note: Information in the data package indicates that Kickstart is an alternate reference name for the product, CID 2000.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

### II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as buildings, floors, walls, ceilings, counters, animal pens/cages, vehicle items (e.g., mats, crates, cabs, wheels), feeding/drinking equipment, and handling/restraining equipment. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare use solution by mixing an appropriate amount of the product with water (1:256 to treat *Salmonella choleraesuis*). Remove all animals and feed from the area. Remove all litter and manure from floors, walls, and surfaces. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the use solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried. Before reuse, thoroughly scrub treated feeding and watering appliances with soap or detergent and

rinse with potable water. Disinfect equipment by immersing equipment in use solution for 10 minutes. Allow to air dry. Fresh disinfecting solution should be made daily.

### III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Microorganisms)

The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis (ATCC 10708) and Staphylococcus aureus (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

### Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are presented in DIS/TSS-2.

### IV COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 459188-01 "Amended Report for AOAC Use-Dilution Method for Kickstart," by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – February 14, 2003 (Amended). HTR Study No. 01-109138-11.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708) in the presence of a 5% organic soil load (horse serum). Three lots (Lot Nos. 101760, 102360, and 102960) of the product, Kickstart, were tested using the AOAC Use-Dilution Method, as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. All product lots were at least 60 days old at the time of testing. A 1:256 dilution of the product was prepared by adding 3.9 mL of the product to 1000 mL of 400 ppm AOAC synthetic hard water (titrated at 405 ppm). Sixty (60) stainless steel cylinder carriers were immersed for 15 minutes in 10 mL of a 48-54 hour old suspension of the test organism. The carriers then were dried for 40 minutes at 37±1°C. The dried carriers were exposed to 10 mL of the use solution for 10 minutes at 20±1°C. After exposure, the carriers were transferred into tubes containing 10 mL of Letheen Broth. After 30 minutes, the carriers were subcultured again into tubes containing Letheen Broth. All tubes were incubated at 37±1°C for 48±2 hours. Following incubation, the tubes were observed for growth or no growth. Controls included dried carrier counts. Neutralization and toxicity evaluation controls were not conducted against *Salmonella choleraesuis*.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The laboratory report also contained efficacy data for studies conducted against Staphylococcus aureus and Pseudomonas aeruginosa. These studies are not discussed in this report, as EPA's January 29, 2003 letter did not request any further information about the studies conducted against these two microorganisms.

### V RESULTS

MRID Number	Organism	No. Exhib	Dried Carrier Count		
		Lot No. 101760	Lot No. 102360	Lot No. 102960	(CFU/carrier)
459188-01	Salmonella choleraesuis	1* - 0/60 2* - 0/6 <b>0</b>	1° - 0/6 <b>0</b> 2° - 0/6 <b>0</b>	1° - 0/60 2° - 0/60	1.3 × 10 <sup>6</sup>

### VI CONCLUSIONS

1. The amended efficacy data (MRID No. 459188-01) do not support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Salmonella choleraesuis* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. The laboratory has failed to provide neutralization data demonstrating that Letheen Broth is an effective neutralizer for the product. Neutralization and toxicity evaluation data were provided against *Staphylococcus aure*us but not against *Salmonella choleraesuis*. Otherwise, no growth was observed in the subcultures of the carriers tested against three lots of the product. All three product lots tested were at least 60 days old at the time of testing. The dried carrier counts were at least 1 x 10<sup>4</sup>.

### VII RECOMMENDATIONS

- 1. The proposed label claims (as supported by MRID No. 459188-01) are not acceptable regarding the use of the product, CID 2000, as a disinfectant against Salmonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. [See the Conclusions Section of this report for more details.] Prior to approving the proposed label, EPA may want to specifically request that the laboratory provide neutralization and toxicity evaluation data against Salmonella choleraesuis. Until adequate efficacy data are submitted for a determination against Salmonella choleraesuis, the use of the phrase "broad spectrum disinfectant" on the proposed label is not acceptable.
- 2. Instructions on the EPA Data Package Record Bean Sheet requested the review of Salmonella choleraesuis and Staphylococcus aureus data. EPA has aiready completed its review of label claims against Staphylococcus aureus. EPA may want to delete reference to Staphylococcus aureus from the Data Review Instructions on the Bean Sheet.

### January 22, 2003

### **MEMORANDUM**

Subject: Secondary Review of Contractor's (DynCorp Systems & Solutions LLC)

Efficacy Review of CID 2000,

EPA Reg. No. 71355-E, Case No. 069188 DP Barcode: D286206

From: Bruce H. Mann

Efficacy Evaluation Team

Product Science Branch (7510C)

To: Marshall Swindell, PM 33/Karen Leavy-Munk

Regulatory Management Team II Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader

**Efficacy Evaluation** 

Antimicrobials Division (7510C)

Applicant: NV CID LINES® SA

8900 leper, Belgium

### Formulation Label:

Active Ingredient(s)	% by wt.
Hydrogen peroxide	26.50
Peroxyacetic acid	
Inert Ingredient(s)	
Total	

### BACKGROUND

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The product, CID 2000 (EPA Reg. No. 71355-E), is a new product. The applicant requested to register the product as a broad spectrum disinfectant and virucide for use on hard, non-porous, non-food contact surfaces on farms and in veterinary hospitals and food processing plants. The label claims that the product is effective in the presence of a 5% organic soil load. Studies were conducted at Southern Microbiology Associates, LLC located at 4204 Edmonton Drive in Bessemer, Alabama 35022; and Hill Top Research, Inc. located on Main and Mill Streets in Miamiville, Ohio 45147.

This data package contained EPA Form 8570-4 (Confidential Statement of Formula), three studies (MRID Nos. 457670-01 through 457670-03), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

Note: Correspondence from the applicant states that CID 2000 (primary name) and Kickstart (additional name) are "identical products towards chemical composition."

Note: The data package included a label for the acid-based sanitizer, CID 2000 (dated-stamped September 12, 2000 by EPA), and a label for the disinfectant, CID 2000 (date-stamped October 1, 2002 by EPA). The formulations for the two products are slightly different. The label for the acid-based sanitizer, CID 2000, appears to be irrelevant to the data package and may be a previous draft of the product label.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

### II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as buildings, floors, walls, ceilings, counters, animal pens/cages, vehicle items (e.g., mats, crates, cabs, wheels); feeding/drinking equipment, and handling/restraining equipment. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare use solution by mixing an appropriate amount of the product with water (1:256 to treat against Salmonella choleraesuls, Staphylococcus aureus; 1:512 to treat against Listeria monocytogenes, Mycoplasma gallinarum, and Salmonella choleraesuis serotype enleritidis; and 1:384 to treat against Infectious Bursal Disease virus and Newcastle Disease virus). Remove all animals and feed from the area. Remove all litter and manure from floors, walls, and surfaces. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with use solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried. Before reuse, thoroughly scrub treated feeding and watering appliances with soap or detergent and rinse with potable water. Disinfect equipment by immersing equipment in use solution for 10 minutes. Allow to air dry. Fresh disinfecting solution should be made daily.

### III AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 104 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Microorganisms)

The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis (ATCC 10708) and Staphylococcus aureus (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different batches. To support products labeled as "disinfectants" for specific microorganisms (other than those microorganisms named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10<sup>4</sup> microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

### Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the

appropriate Recommended Method at the same hard water tolerance level. These Agency standards are presented in DIS/TSS-2.

### IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 457670-01 "Virucidal Evaluation of Kick-Start for Use on Inanimate Environmental Surfaces: Test for Efficacy Against Infectious Bursal Disease Virus," by Hazel R. Bowdon. Study conducted at Southern Microbiology Associates, LLC. Study completion date – May 23, 2002.

This study was conducted against Infectious Bursal Disease virus (Strain D78, ATCC VR-2041), using chick embryo fibroblasts as the host system (source of host not indicated). Two lots (Lot Nos. 104760 and 200260) of the product, Kickstart, were tested according to the EPA Pesticide Assessment Guidelines, 1982. A use solution was prepared by diluting 1 mL of the product in 38.3 mL of 402.5 ppm hard water (a 1:384 dilution). The stock virus titer contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over approximately 23 to 28 cm² on the bottoms of sterile glass Petri dishes. The virus films were air-dried at 20-25°C for 20-45 minutes. For each lot of product, virus films were exposed to 2.0 mL of the use solution at 23°C. The exposure was terminated after 9.5 minutes by passage through Sephadex gel columns. This procedure lasted approximately 30 seconds, which increased the exposure to 10 minutes. The Sephadex filtered solutions were diluted serially in 1-log dilutions. Each serial dilution was added in a 0.2 mL quantity to each of 4 wells of chick embryo fibroblasts. Controls included cytotoxicity and neutralization. Viral and cytotoxicity titers were calculated by the Reed and Muench method (1938).

2. MRID 457670-02 "AOAC Use-Dilution Method" for Kickstart, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – November 20, 2001

This study was conducted against Staphylococcus aureus (ATCC 6538), Salmonella choleraesuis (ATCC 10708), and Pseudomonas aeruginosa (ATCC 15442). Three lots (Lot Nos. 101760, 102360, and 102960) of the product, Kickstart, were tested using the AOAC Use-Dilution Method, as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was tested in the presence of a 5% organic soil load (horse serum). All product lots were at least 60 days old at the time of testing with one exception; it is unconfirmed whether at least one of the product tots tested against Pseudomonas aeruginosa (at a 1:512 dilution) was at least 60 days old at the time of testing. A 1:256 dilution of the product (using 400±10 ppm AOAC synthetic hard water (titrated value not indicated)) was tested against Staphylococcus aureus and Salmonella choleraesuis. A 1:384 and 1:512 dilution of the product (using 400±10 ppm AOAC synthetic hard water (titrated value not indicated)) was tested against Pseudomonas aeruginosa. Polished stainless steel cylinder carriers were immersed for 15 minutes in 10 mL of a 48-54 hour old suspension of the test organism. The carriers then were dried for 40 minutes at 37±1°C. The carriers were exposed to 10 mL of the use solution for 10 minutes at 20±1°C. After exposure, the carriers were transferred into tubes containing 10 mL of Letheen Broth. After 30 minutes, the carriers were subcultured again into tubes containing Letheen Broth. All tubes were incubated at 37±1°C for 48±2 hours. Following incubation, the tubes were observed for growth or no growth. Controls included phenol resistance, neutralization evaluation, cytotoxicity, and dried carrier counts.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 457670-03 "AOAC Use-Dilution Method" for Kickstart, by Kathleen A. Baxter. Study conducted at Hill Top Research, Incorporated. Study completion date – February 1, 2002.

This study was conducted against Escherichia coli (ATCC 11229), Listeria monocytogenes (ATCC 15313), Mycoplasma gallinarum (ATCC 19708), and Salmonella choleraesuis, serotype enteritidis (ATCC 13076). Two lots (Lot Nos. 101760 and 102360) of the product, Kickstart, were tested using the AOAC Use-Dilution Method, as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was tested at a 1:512 dilution in 400±10 ppm AOAC synthetic hard water (titrated value not indicated) in the presence of a 5% organic soil load (horse serum). Ten polished stainless steel cylinder carriers were immersed for 15 minutes in 10 mL of a suspension of the test organism. The carriers then were dried for 40 minutes at 37±1°C. The carriers were exposed to 10 mL of the use solution for 10 minutes at 20±1°C. After exposure, the carriers were transferred into tubes containing 10 mL of Letheen Broth (for Escherichia coli and Salmonella choleraesuis, serotype enteritidis), Brain Heart Infusion Broth (for Listeria monocytogenes), or Mycoplasm Medium (for Mycoplasma gallinarum). After 30 minutes, the carriers were subcultured again into tubes containing neutralizing medium. All tubes were incubated at 37±1°C for 48±2 hours except tubes containing Mycoplasma gallinarum which were incubated at 37±1°C with 5% CO<sub>3</sub> for 48±2 hours. Following incubation, the tubes were observed for growth or no growth. Controls included phenol resistance, neutralization evaluation, cytotoxicity, and dried carrier counts.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

### V RESULTS

MRID	Organism		Results		
			Lot No. 104760	Lot No. 200260	Control (TCID <sub>50</sub> /0.2 mL)
457670-01	Bursal dilution	10 <sup>-1</sup> and 10 <sup>-2</sup> dilution	Cytotoxicity present	Cytotoxicity present	5.5
		10 <sup>-3</sup> to 10 <sup>-6</sup> dilution	Complete inactivation	Complete inactivation	
	D78, VR- 2041)	TCID <sub>50</sub> /0.2 mL	<b>≤2.</b> 5	≤2.5	
		Log reduction	≥3.0	≥3.0	

MRID Number	Organism	No. Exh	No. Exhibiting Growth/Total No. Tested			
		Lot No. 101760	Lot No. 102360	Lot No. 102960	(CFU/carrier)	
457670- 02	Staphylococcus aureus	1° - 1/60 2° - 0/60	1° - 0/60 2° - 0/60	1° - 0/60 2° - 0/60	7.4 x 10 <sup>6</sup>	
<b>4</b> 57670- 02	Pseudomonas aeruginosa 1:512 in 400 ppm	1° - 2/60 2° - 3/60	1° - 1/60 2° - 3/60	1° - 2/60 2° - 2/60	5.2 x 10 <sup>6</sup>	
	1:384 in 405 ppm	1° - 1/60 2° - 2/60	1° - 1/60 2° - 1/60	1° - 0/60 2° - 3/60	8.2 x 10 <sup>6</sup>	
457670- 02	Salmonella choleraesuis	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1.3 x 10 <sup>6</sup>	

MRID Number	Organism	No. Exhibiting	Dried Carrier Count		
	Lot No. 101760		Lot No. 102360	(CFU/carrier)	
457670-03	Escherichia colì	1° - 10/10 2° - 10/10	1° - 10/10 2° - 10/10	2.2 x 10 <sup>7</sup>	
	Listeria monocytogenes	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1.6 x 10 <sup>6</sup>	
	Mycoplasma gallinarum	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	6.8 x 10⁵	
	Salmonella choleraesuis, serotype enteritidis	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1.5 x 10 <sup>6</sup>	

### VI CONCLUSIONS

- 1. The submitted efficacy data (MRID No. 457670-01) support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with virucidal activity when tested against Infectious Bursal Disease virus (Strain D78, ATCC VR-2041) on hard, non-porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:384 dilution. Cytotoxicity was observed at the 10<sup>-1</sup> to 10<sup>-2</sup> dilutions. Complete inactivation (no growth) was observed in the 10<sup>-3</sup> to 10<sup>-6</sup> dilutions. A 3-log reduction in titer was demonstrated beyond the cytotoxic level. The recoverable virus titer was at least 10<sup>4</sup>.
- 2. The submitted efficacy data (MRID No. 457670-02) support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when

tested against Staphylococcus aureus on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on at least 59 of 60 carriers for each product lot tested. All three product lots were at least 60 days old at the time of testing. The dried carrier counts were at least 1 x 10<sup>4</sup>. The neutralization evaluation control showed positive growth.

3. The submitted efficacy data (MRID No. 457670-02) do not support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Salmonella choleraesuis* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on at least all 10 carriers tested; however, DIS/TSS-1 requires testing of 60 carriers. All three product lots were at least 60 days old at the time of testing. The dried carrier counts were at least 1 x 10<sup>4</sup>. The neutralization confirmation control showed positive growth against *Staphylococcus aureus*.

Note: The laboratory may have incorrectly reported the number of carriers tested. The test summary results [page 7 of the MRID] indicated 60 carriers were tested for Salmonella choleraesuis, and test procedures [page 27 of the MRID] called for testing of 60 carriers. However, the Report Form [page 9 of the MRID] indicates that 10 carriers were tested.

- 4. The submitted efficacy data (MRID No. 457670-02) do not support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Pseudomonas aeruginosa* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a dilution of 1:384 or 1:512. The product was not effective on at least 59 of 60 carriers for the product lots tested.
- 5. The submitted efficacy data (MRID No. 457670-03) appear to support the use of the product, CID 2000 (primary name) or Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Listeria monocytogenes*, *Mycoplasma gallinarum*, and *Salmonella choleraesuis*, serotype *enteritidis* on hard, non-porous surfaces in the presence of a 5% organic soil toad (horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:512 dilution. The product was effective on 10 of 10 carriers for each product lot tested. The dried carrier counts were above 1 x 10<sup>4</sup>, as required. The neutralization effectiveness control showed positive growth against *Mycoplasma gallinarum*.
- 6. The submitted efficacy data (MRID No. 457670-03) do not support the use of product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Escherichia coli* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:512 dilution. The product was not effective on 10 of 10 carriers for each product lot.

### VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, CID 2002 (primary name) and Kickstart (additional name), as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes:

<u>Organisms</u>	<u>Dilution</u>	MRID No.
Infectious Bursal Disease virus		
(Strain D78, ATCC VR-2041)	1:384	MRID No. 457670-01
Listeria monocytogenes	1:512	MRID No. 457670-03
Mycoplasma gallinarum	1:512	MRID No. 457670-03
Salmonella choleraesuis, serotype enteritidis	1:512	MRID No. 457670-03
Staphylococcus aureus	1:256	MRID No. 457670-02

2. The proposed label claims (as supported by MRID No. 457670-02) are not acceptable regarding the use of the product, CID 2002 (primary name) and Kickstart (additional name), as a disinfectant against *Salmonella choleraesuis* on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. The applicant needs to provide the Agency with a clanification by or from the laboratory as to whether 10 or 60 carriers were tested in this study. If 60 carriers were tested, then, the applicant needs to provide the Agency additional data that will demonstrate neutralization against *Salmonella choleraesuis*. If 60 carriers were not tested, then proposed label claims regarding *Salmonella choleraesuis* and product use as a broad-spectrum disinfectant need to be removed from the label. Adequate and acceptable efficacy must be generated and submitted for an efficacy determination (refer to item (b) of DIS/TSS-1 enclosure for efficacy requirements).

Until adequate efficacy data are submitted for a determination against Salmonella choleraesuis, the use of the phrase 'broad spectrum disinfectant" at the top of page #1 is considered unacceptable. The indicated label comments are applicable for the proposed label "CID 2000" pinpunched 10-01-2002.

- 3. Efficacy data submitted for the following microorganisms <u>do not</u> support effectiveness of the product at a 10 minute contact time in the presence of a 5% organic soil load. Eventhough, the proposed label <u>does not</u> include label claims for these microorganisms, a listing of the proposed test microorganisms is considered unacceptable. Until adequate efficacy data are submitted in support of effectiveness against *Pseudomonas aeruginosa*, the proposed label claim for veterinary hospitals is considered unacceptable. The comment is applicable for page #3 on the proposed label "CID 2000" pinpunched 10-01-2002.
- Pseudomonas aeruginosa, as supported by MRID No. 457670-02
- Escherichia coli, as supported by MRID No. 457670-03
- 4. The proposed label includes claims of product efficacy against Newcastle Disease virus at a 1:384 dilution. The submitted data package provided to the Agency <u>do not</u> include any efficacy studies in support of this proposed label claim. Therefore, the proposed label claim against the microorganism, New Castle Disease virus, is unacceptable and must be removed from the product proposed label "CID 2000", pinpunched 10-01-2002.

DP #: (308939)Decision #: 216261

## DATA PACKAGE BEAN SHEET

Date: 05-Oct-2004 Page 1 of 2

## \* \* \* Registration Information \* \* \*

Registration:	71355-E - CID 2000			And the second s			
Company:	71355 - CID LINES N.V.						
Risk Manager:	RM 33 - Marshall Swindel	- (703) 308-6341 Room#	CM-2 308H				
Risk Manager Reviewer:	Karen Leavy KLEAVY	<u></u>		_			
Sent Dale:	16-Sep-2004	Calculated Due Dat	te: 14-Jan-2005	Edited Due Date:			
Type of Registration:	Product Registration - Sec	lion 3					
Action Desc:	(188) ADDITIONAL USE:	NEW REGISTRATION; OL	D INGREDIENT;ME-	TDO:			
Ingredients:	000595, Hydrogen peroxide(20%)						
	* * *	Data Package In	formation * * '	*			
Expedite: 🔘 Yes 🌑 No		Date Se	nt: 05-Oct-2004	Due Back:			
DP Ingredient:	000595, Hydrogen peroxic	fe	<u></u>				
DP Title:							
CSF Included:	• Yes () No L	abel included:  Yes	No Parent C	OP #:			
Assigned To	<u> </u>	Date In	Date Dut				
Organization: AD / P	S8	10/6/04		Administrative Due Date: 06-Jan-2005			
Team Name: EET	<del>مس</del> ندر المستنبيرين المستندر	10/4/04		Negotiated Due Date: 12/14/09			
iewer Name:	<u>narcies</u>	12/06/14	12/03/04	Projected Completion Date: 11/30/04			
Contractor Name:				/ / ·			
	* * * St	udies Sent for R	eview * * *				
		No Studies					
	* * * Additional	Data Package fo	r this Decisio	n * * *			
		Printed on Page 2					
	* * * Dat	a Package Instri	uctions * * *				

PLEASE REVIEW THE SUBMITTED AGAC USE DILUTION TEST AND PROPOSED LABELING ADMIN DUE DATE 01/14/04, ETT DUE DATE 12/14/04, ACTION CODE 188, FOPA

SUBMISSION BAR CODE # S 6 3-5-3-36 REVIEWERK LEAVY-MUNK

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FILE SYMBOL/REG NO.	7/355	E PM S	33 A	STION COD	E 189
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REVIEW(S) REQUESTED	DATA	DATE	DUE		
REVIEW(S) REQUESTED	DATA	DATE SENT	DUE DATE		
REVIEW(S) REQUESTED— CHEMISTRY  EFFICACY	DATA	DATE SENT	DUE DATE		
REVIEW(S) REQUESTED— CHEMISTRY EFFICACY TOXICOLOGY	DATA	DATE SENT	DUE DATE		
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AUS-1.5 2003.

HESPONSE, DATE



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 1 5 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Olivia Laird Agent for, NV CID Lines SA 501 South Lincoln Avenue Sterling, VA 20164-2024

Subject: CID 2000

EPA File Symbol 71355-E

Your Submission Dated April 21st, 2003 EPA Received Date April 21st, 2003

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, is unacceptable for the following reasons:

The amended efficacy data (MRID No. 459188-01)do not support the use of the product, CID 2000 (primary name) and Kick start (additional brand name), as a disinfectant with bactericidal activity when tested against Salmonella cholcraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load (horse scrum) and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. The laboratory has failed to provide neutralization data demonstrating that Letheen Broth is an effective neutralizer for the product. Neutralization and toxicity evaluation data were provided against Staphylococcus aureus but not against Salmonella cholcraesuis. Otherwise, no growth was observed in the subcultures of the carriers tested against three lots of the product. All three product lots tested against three lots of the product. All three product lots tested were at least 60 days old at the time of testing. The dried carrier counts were at least 1x10.

The proposed label claims (MRID No. 459188-01) are not acceptable regarding the use of the product, CID 2000, as a disinfectant against Salmonella choleraesuis on hard, non-porous surfaces in the presence of 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution.

Provide neutralization and toxicity evaluation data against Salmonella choleraesuis. Until adequate efficacy data are submitted for a determination against Salmonella choleraesuis, the use of the phrase, "broad spectrum disinfectant" on the proposed label is not acceptable.

All DIS/TSS that are referenced in this efficacy review can be retrieved from the following internet address: http://acc.edu/info/nain/distss.htm.

A copy of the complete efficacy review is enclosed for your review.

The product may not be lawfully distributed in interstate commerce until it is registered.

The Agency reserves a full label review until the above discrepancies have been clarified.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIBES AND TOXIC SUBSTANCES

July 16, 2003

### **MEMORANDUM:**

Subject: Effica

Efficacy Review for EPA Reg. No.: 71355-E, "CID 2000"

DP Barcode: D290087 Case No: 069188

From:

Emily Mitchell, M.S., Team Leader Easily, Mitchell 1/16/08
Efficacy Evaluation Team

Efficacy Evaluation Team Product Science Branch

Antimicrobials Division (7510C)

To:

Marshall Swindell PM33/Karen Leavy-Munk

Regulatory Management Branch I Antimicrobials Division (7510C)

Applicant:

**NV CID Lines SA** 

Waterpoortstraat 2 B 8900 leper

Belgium-Europe

### Formulation From Label:

Active Ingredient(s)	<u>% by wt.</u>
Hydrogen peroxide	26.5%
Peroxyacetic acid	4.9%
Inert Ingredient(s)	<u>68.6%</u>
Total	100.0%

### BACKGROUND

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The product, CID 2000 (EPA Reg. No. 71355-E), is a new product. The applicant requested to register the product as a broad spectrum disinfectant (bactericide, virucide) for use on hard, non-porous, non-food contact surfaces on farms and in veterinary hospitals and food processing plants. The label claims that the product is effective in the presence of "400 ppm AOAC synthetic hard water with 5% soil load." This data package is a re-submission of information in response to an EPA letter dated January 29, 2003. In its letter, EPA notified the applicant's representative that the submitted efficacy data did not support the use of the product against Salmonella choleraesuis. EPA requested clarification of whether 10 or 60 carriers were tested in the study against Salmonella choleraesuis. In addition, EPA requested additional data demonstrating effectiveness of the neutralizer against Salmonella choleraesuis if 60 carriers were tested. The applicant submitted amended efficacy data for the study against Salmonella choleraesuis. The study was conducted at Hill Top Research, Inc., located on Main and Mill Streets, Miamiville, OH 45147.

This data package contained a copy of an EPA letter to the applicant's representative (dated January 29, 2003), EPA Form 8570-4 (Confidential Statement of Formula), one study (MRID No. 459188-01), Statements of No Data Confidentiality Claim for the study, and the proposed label (pin-punched 10/1/02, by EPA).

Note: The data package also included a label for the acid-based sanitizer, CID 2000 (pin-punched 9/12/00, by EPA). The label for the acid-based sanitizer, CID 2000, appears to be irrelevant to the data package and may be a previous draft of the product label.

Note: Information in the data package indicates that Kickstart is an alternate reference name for the product, CID 2000.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

### II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as buildings, floors, walls, ceilings, counters, animal pens/cages, vehicle items (e.g., mats, crates, cabs, wheels), feeding/drinking equipment, and handling/restraining equipment. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare use solution by mixing an appropriate amount of the product with water (1:256 to treat Salmonella choleraesuis). Remove all animals and feed from the area. Remove all litter and manure from floors, walls, and surfaces. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the use solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried. Before reuse, thoroughly scrub treated feeding and watering appliances with soap or detergent and

rinse with potable water. Disinfect equipment by immersing equipment in use solution for 10 minutes. Allow to air dry. Fresh disinfecting solution should be made daily.

### III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Microorganisms)

The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis (ATCC 10708) and Staphylococcus aureus (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

### Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are presented in DIS/TSS-2.

### IV COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 459188-01 "Amended Report for AOAC Use-Dilution Method for Kickstart," by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – February 14, 2003 (Amended). HTR Study No. 01-109138-11.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708) in the presence of a 5% organic soil load (horse serum). Three lots (Lot Nos. 101760, 102360, and 102960) of the product, Kickstart, were tested using the AOAC Use-Dilution Method, as described in the AOAC Official Methods of Analysis, 15<sup>th</sup> Edition, 1990. All product lots were at least 60 days old at the time of testing. A 1:256 dilution of the product was prepared by adding 3.9 mL of the product to 1000 mL of 400 ppm AOAC synthetic hard water (titrated at 405 ppm). Sixty (60) stainless steel cylinder carriers were immersed for 15 minutes in 10 mL of a 48-54 hour old suspension of the test organism. The carriers then were dried for 40 minutes at 37±1°C. The dried carriers were exposed to 10 mL of the use solution for 10 minutes at 20±1°C. After exposure, the carriers were transferred into tubes containing 10 mL of Letheen Broth. After 30 minutes, the carriers were subcultured again into tubes containing Letheen Broth. All tubes were incubated at 37±1°C for 48±2 hours. Following incubation, the tubes were observed for growth or no growth. Controls included dried carrier counts. Neutralization and toxicity evaluation controls were not conducted against *Salmonella choleraesuis*.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The laboratory report also contained efficacy data for studies conducted against *Staphylococcus* aureus and *Pseudomonas aeruginosa*. These studies are not discussed in this report, as EPA's January 29, 2003 letter did not request any further information about the studies conducted against these two microorganisms.

# V RESULTS

MRID Number	Organism	No. Exhib	Dried Carrier Count		
		Lot No. 101760	Lot No. 102360	Lot No. 102960	(CFU/carrier)
459188-01	Salmonella choleraesuis	1° - 0/60 2° - 0/60	1° - 0/60 2° - 0/60	1° - 0/60 2° - 0/60	1.3 × 10 <sup>6</sup>

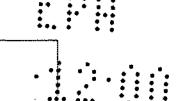
# VI CONCLUSIONS

1. The amended efficacy data (MRID No. 459188-01) do not support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Salmonella choleraesuis* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. The laboratory has failed to provide neutralization data demonstrating that Letheen Broth is an effective neutralizer for the product. Neutralization and toxicity evaluation data were provided against *Staphylococcus aureus* but not against *Salmonella choleraesuis*. Otherwise, no growth was observed in the subcultures of the carriers tested against three lots of the product. All three product lots tested were at least 60 days old at the time of testing. The dried carrier counts were at least 1 x 10<sup>4</sup>.

# VII RECOMMENDATIONS

- 1. The proposed label claims (as supported by MRID No. 459188-01) are not acceptable regarding the use of the product, CID 2000, as a disinfectant against Salmonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. [See the Conclusions Section of this report for more details.] Prior to approving the proposed label, EPA may want to specifically request that the laboratory provide neutralization and toxicity evaluation data against Salmonella choleraesuis. Until adequate efficacy data are submitted for a determination against Salmonella choleraesuis, the use of the phrase "broad spectrum disinfectant" on the proposed label is not acceptable.
- 2. Instructions on the EPA Data Package Record Bean Sheet requested the review of Salmonella choleraesuis and Staphylococcus aureus data. EPA has already completed its review of label claims against Staphylococcus aureus. EPA may want to delete reference to Staphylococcus aureus from the Data Review Instructions on the Bean Sheet.

# **CID 2000**



CID 2000 is a peracetic acid-based sanitizer developped for the cleaning and decontamination of drinking water systems for :

- 1. broilers and layers
- 2. turkeys
- 3. pigs

# Active ingredients:

Peracetic acid Hydrogen peroxide Inert ingredients 5 % (by wt) 20 % <u>75 %</u> 100%

# KEEP OUT OF REACH OF CHILDREN

# DANGER

# STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

JF ON SKIN.: Rinse skin immediately with plenty of soap and water for 15-20 minutes. . Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

# SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No:

EPA Establishment No: 71355-BEL-001

Batch No : see top of bottle Expiry Date : see top of bottle

# MANUFACTURED BY:

THE PROPERTIONAL PROPERTY OF A SAME

Waterpoortstraat 2 - B 8900 IEPER BELGIUM - EUROPE

Phone: 011 32 57 217877 - Fax: 011 32 57 217879 Website: http://www.cidlines.be - e-mail: cidlines@cidlines.be

Nel contents: 1 gal

# PRECAUTIONARY STATEMENTS

# HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROStVE. Causes irreversible eye damage and skin burns. May be fatat if inhaled or absorbed through the skin. Harmfult if swallowed Do not breathe vapors. Do not got in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not onter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

## **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## PHYSICAL AND CHEMICAL HAZARDS:

STRONG OXIDIZING AGENT. Corrosive, Mix only with water, Product must be diluted in accordance with label directions prior to use. CID 2000 is not combustible, however, at temperatures exceeding 158°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

## **DIRECTIONS FOR USE:**

It is a violation of Federat Law to use this product in a manner inconsistent with its labeling

CID 2000 peracetic acid sanitizer is recommended for use in drinking water systems as a cleaning agent of the entire drinking water system (pipelines, nipples, bell-drinkers, ...) between the flocks, and as a drinking water sanitizer during production.

CID 2000 is effective against bacteria and fungl and prevents formation of stimes during production.

1. Cleaning of drinking water systems :

Between the flocks: let circulate a 1:50 solution of CID 2000. Use circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of 4-6 hours. Drain thoroughly and rinse with potable water until clear water comes out of the drinking water system. Repeat treatment as required to maintain control.

For acidification and decontamination of the drinking water during production:
 Use CID 2000 at a dilution of 1:2500 to 1:3000 during 2 to 3 days a week every other day, or in delicate periods 3 to 4 consecutive days. Use circulation techniques as appropriate to the equipment.

Stop adding CID 2000 24 hours before vaccination and medical treatments.

#### REMARK:

Use CID 2000 with pumps fully made out of Teffon® (if not possible : make a 1:100 predilution before passing the pump)

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and colors statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchandability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be sofety responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings of cautions.

Buyer's exclusive remedy and manufacturer's or soller's exclusive flability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, wither or not such liability in based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturar or seller be liable for special, indirect or consequential claimages resulting from the use or handling of this product.

# CID 2000

# CONCENTRATED BROAD SPECTRUM DISINFFCTANT

Active ingredients:

HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients 26 5% 4 9% 68 6 %

# KEEP OUT OF REACH OF CHILDREN

# DANGER

Taken de para Par kerantah da da hara sa haraksi Statemera p

# CID 2000 is effective against:

- Bactena: Salmonella Cholerasuis (ATCC 18708), Staphylococcus aureus (ATCC 6538) in a dilution of 1-256 in 400ppm AOAC synthetic hard water with 5% soil load, Listeria monocytogenes (ATCC 15313). Mycoplasma gallinarum (ATCC 19708), Sulmonella Chloreasuis seratype enlouidis (ATCC 13076) in a dilution of 1-512 in 400ppm AQAC synthetic hard water with 5% soil load.
- Virus: Intechous Bursal Disease of Chickens, (ATCC D78 VR-2041). Newcastle Disease (Spatas) shain 5390161 in a district of 1, 394 in 400ppm AOAC synthetic hard water with 5% soil load.

EPA Reg N 71366

NET CONTENTS 1 - 5 gallonisi

BATCHN

EPA Est Nº 71355-BEL-CUI

EXPIRY DATE

## APPLICATION:

Disinfection of non-food surfaces, farm, animal, and politry housing facilities and equipment.

- Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3 Food processing plants (staughterhouses).
- 4. Trays, racks, carts, chick boxes, cages and other hard surfaces.
- 5. Trucks and other vehicles.
- 6 Vetermary besoitals.

# FIRST AID STATEMENTS

IF IN EYES. Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin huntediately with plenty of soap and water for 15-20 minutes. Get medical attention

If SWALLOWED Call a doctor or get medical attention. Do not induce vorming or give anything by mouth to an unconscious person. Orink promptly a targe quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN Probable microsal damage may confiamilicate the use of qu



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## PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective ckithing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with some and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

## PHYSICAL AND CHEMICAL HAZARDS

**STRONG OXIDIZING AGENT.** Corrosive, Mix only with water, Product must be diluted in accordance with label directions prior to use. CID 2000 is not combustible, however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could mitrate combustion.

# **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds. Iish and equatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidence contact your State Water Board or Regional Office of the EPA.

## DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labelling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-perous surfaces: stainless, galvanised and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, brick walls, staidwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water hefore reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry
- F Fresh disinfecting solution should be made daily

# 2. Hatcheries:

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, treys, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Satisfie all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed and determined and determined to the solution should be made daily or if visibly solled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging malenals must be removed from the room to carefully protected. Pre-clean surfaces it visibly scited. Disinfect hard, non-porous surfaces by applying



NV CID LINES SA - Waterpoonstrant 2 8900 IEPER - 82LGIUM - EUROPE let 011 32 57 217877 13x 011 32 57 217879

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the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughty wet for 10 minutes. Allow to air dry. A potable water ringe is required for all surfaces that come into consact with food.

# 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectiant solution wat for 10 minutes. Allow to air dry

# 5. Veterinary hospitals:

For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Clean all surfaces if visibly soiled. Saturate surfaces with the disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughty scrub freated feeding and watering equipment with soap or delorgent and ribse with potable water before reuse. Fresh disinfecting solution should be made daily or if visibly soiled.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or food by storage and disposal

Storage: Never return CID 2000 to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and motors. Contamination and impurities will reduce shelf-life and can induce decomposition, in case of decomposition, isolate container, donse container with cool water and dilute CID 2000 with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallots.

Procedures for leak of split: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combostible and organic materials away. Flosh splited material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of pesticide. Posticide wastes are actitely hazardous. Improper disposal of excess pesticide, spray mixturo or rinshte is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 voluntes of water followed by discharge into suitable treatment system in acceptance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to discharged, should be disposed of as hezardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container. Triple rinse. Then offer for recycling or puricture and dispose in a sanitary land\*!! Disposal by incineration, or if allowed by state and local authorities, by burning, if burned, stay out of smoke

Note: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before processing with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label (its) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in acceptance with such checitions; and (c) that the checitions, warrangs and of training to its label are based upon responsible popul's evaluation of reasonable tests of effectiveness are of training to insential nor popular. The manufacturer neither makes not intends, nor coos it subhorize any agent or regressentative to make, any other warrantes. The manufacturer neither makes not intends, nor coos it subhorize any agent or regressentative to make, any other warrantes, expressed or implies, and it expressly excludes and disclaims all implied warrantes or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which test from the use of this product in any manner which is inconsistent with the label direction, warrings or consoled. Buyer's exclusive rainedy and manufacturers or seller's exclusive diability for any and all claims, losses, compage, or injuries resulting from the use or handling of this product, whether or not such tiability is based in the contract, negligence, stret liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of or the repayment of the purchase according to the quantity of product with tespect to when camages are coinfined. In necessarial shall manufacturer or solder be trace for special manages are coinfined to me event shall manufacturer or solder be trace for special manages.



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e-mail <u>Cidines@copues pa</u>

HILL TOP RESEARCH, INC.
MAIN AND MILL STREETS
MIAMIVILLE, OHIO 45147

PROTOCOL DEVIATION #1

AOAC Use-Dilution Method

HTR STUDY NO.:

01-109138-11

SPONSOR & ADDRESS:

CID LINES®
Waterpoortstraat 2

8900 leper, Belgium

SPONSOR'S REPRESENTATIVE:

Vincent Catry

# PROTOCOL DEVIATION:

The hard water prepared on September 13, 2001 was 0.11 pH units below the specification. In the opinion of the Study Director, the deviation did not have an adverse effect on the outcome of the study.

APPROVED FOR: HILL TOP RESEARCH, INC.

BY:

Kathleen A. Baxter, B.S.

Study Director

Microbiological Services Division

Date

February 14, 2003 Page 37 of 37

# TRANSMITTAL DOCUMENT

# 1. NAME AND ADDRESS OF SUBMITTER & SPONSOR

SUBMITTER
LAIRD'S REGULATORY CONSULTANTS, INC.
501 SOUTH LINCOLN AVENUE
STERLING, VIRGINIA 20164-2024

**SPONSOR** 

NV CID LINES S.A. WATERPOORTSTRAAT 2 8900 IEPER, BELGIUM

# 2. REGULATORY ACTION TO BE TAKEN

**Submission of Additional Efficacy Data** 

EPA FILE SYMBOL/REG. NO.: 71355-E

PRODUCT NAME: CID 2000 (primary name)/Kickstart (additional name)

TRANSMITTAL DATE

April 21, 2003

3. LIST OF SUMITTED STUDIES

Volume 1: Efficacy-AOAC Use-Dilution Method, HTR Study #01-109138-11 45918801

COMPANY OFFICIAL

for VINCENT CATRY

PM31

COMPANY CONTACT: OLIVIA D. LAIRD

Phone: (703) 471-6590

FAX: (703) 471-6269



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20160

JAN 2 9 2003

OFFICE OF PREVENTION, PRSTICIOES AND TOXIC SUBSTANCES

Ms. Olivia Laird CID Lines c/o Laird's Regulatory Consultants 501 South Lincoln Avenue Sterling, VA 20164-2024

Subject: CID 2000

EPA File Symbol 71355-E

Your Application Dated September 27th, 2002

EPA Received Date October 1", 2002

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the following reasons:

The submitted efficacy data(MRID No. 457670-02) do not support the use of the product, CID 2000, as a disinfectant with bactericidal activity when tested against Salmonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load(horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on at least all 10 carriers tested:however, DIS/TSS-1 requires testing of 60 carriers. All three product lots were at least 60 days old at the time of testing. The dried carrier counts were at least at 1x10°. The neutralization confirmation control showed positive growth against Staphylococcus aureus.

Please note: The laboratory may have incorrectly reported the number of carriers tested. The test summary results (page 7 of the MRID) indicated 60 carriers were tested for Salmonella choleraesuis, and test procedures (page 27 of the MRID) called for testing of 60 carriers. However, the Report Form(page 9 of the MRID) indicates that 10 carriers were tested.

The submitted efficacy data (MRID No. 457670-02) do not support the use of the product, CID 2000, as a disinfectant with bactericidal activity when tested against *Pseudomonas* aeruginosa on hard, non-porous surfaces in the persence of a 5% organic soil load(horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a dilution of 1:38 or 1:512. The product was not effective on at least 59 of 60 carriers for the product lots tested.

The submitted efficacy data(MRID No. 457670-03) do not support the use of product, CID 2000, as a disinfectant with bactericidal activity when tested against *Escherichia coli* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:512 dilution. The product was not effective on 10 of 10 oarriers for each product lot.

JUN 10 '03 10:02

PAGE. 12137

703 308 6467

# Acceptable Data

The submitted efficacy data(MRID No. 457670-010) supports the use of the product. CID 2000, as a disinfectant with virucidal activity when tested against Infectious Bursal Disease virus(strain D78, ATCC VR-2041) on hard, non-porous hard surfaces in the presence of a 5% organic soil load (fetal bovine serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:384 dilution. Cytoxicity was observed at the 10th 10th dilutions.

ANTIMIORODIAND NT.

The submitted efficacy data(MRID No. 457670-02) supports the use of the product, CID 2000, with bactericidal activity when tested against Staphylococcus aureus on hard, non-porous surfaces in the presence of a 5% organic soil load(horse serum) and 400 ppm hard surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on least 59 of 60 carriers for each product lot tested. All three product lots were at neutralization evaluation control showed positive growth.

The submitted efficacy data(MRID No. 457670-03) appear to support the use of the product, CID 2000, as a disinfectant with bactericidal activity when tested against Listeria monocytogenes, Mycoplasma gallinarum, and Salmonella choleraesuls, serotype enteritidis on hard, non-porous surfaces in the presence of a 5% organic soil load(horse serum) and 400 ppm hard water for a contact time of 10 minutes at 1:512 dilution. The product was not effective on 10 of 10 carriers for each product lot. The dried carrier counts were above 1x10, as required. The neutralization effectiveness control showed positive growth against Mycoplasma gallinarum.

# Labeling

The proposed label claims( as supported by MRID No. 457670-02) are not acceptable regarding the use of the product, CID 2000, as a disinfectant against Samonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. Provide the Agency with a clarification by or from the laboratory as to whether 10 or 60 carriers were tested in this study. If 60 carriers were tested, then provide the Agency additional data that will demonstrate neutralization against Salmonella choler aesuis. If 60 carriers were not tested, then the proposed label claims regarding Salmonella choleraesuis and product use as a "broad spectrum disinfectant" needs to be removed from the label. Adequate and acceptable efficacy data must be generated and submitted for an efficacy determination(refer to item(b)) of DIS/TSS-1 enclosure requirements.

Until adequate and acceptable efficacy data are submitted for a determination against Salmonella choleraesuis, the use of the phrase "broad spectrum disinfectant" at the top of page #1 is considered unacceptable. The indicated label comments are applicable for the proposed label, CID 2000, pinpunched 10-01-2002.

However, the proposed label claims are acceptable regarding the use of the product, CID 2000, as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes.

Organisms	<u>Dilution</u>	MRID No.
Infectious Bursal Disease virus (Strain D78, ATCC VR-20410)	1:384	MRID No. 457670-01
Listeria monocytogenes	1:512	MRID No. 457670-03
Mycoplasma gallinarum	1:512	MRID No. 457670-03
Salmonella choleraesuis	1:512	MRID No. 457670-03
Stapylococcus aureus	1:256	MRID No. 457670-02

Revise the First Aid statements as per PR Notice 2001-1.

A complete copy of the science review is enclosed for your records.

The product may not be lawfully distributed in interstate commerce until it is registered.

The Agency reserves a full label review until the above discrepancy have been clarified.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division (7510C)

BOCC 4.

# TRANSMITTAL DOCUMENT

# 1. NAME AND ADDRESS OF SUBMITTER & SPONSOR

SUBMITTER LAIRD'S REGULATORY CONSULTANTS, INC. 501 SOUTH LINCOLN AVENUE STERLING, VIRGINIA 20164-2024

**SPONSOR** 

NV CID LINES S.A. WATERPOORTSTRAAT 2 8900 IEPER, BELGIUM

# 2. REGULATORY ACTION TO BE TAKEN

**Submission of Additional Efficacy Data** 

EPA FILE SYMBOL/REG. NO.: 71355-E

PM31/ PRODUCT NAME: CID 2000(primary name)/Kickstart(additional name)

TRANSMITTAL DATE

April 21, 2003

3. LIST OF SUMITTED STUDIES

Volume 1: Efficacy-AOAC Use-Dilution Method, HTR Study #01-109138-11 45918801

**COMPANY OFFICIA** 

COMPANY CONTACT: OLIVIA D. LAIRD

Phone: (703) 471-6590

FAX: (703) 471-6269

DP BARCODE: D290087

CASE: 069188 DATA PACKAGE RECORD DATE: 05/16/03 SUBMISSION: S635336 BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 189 RESB FORA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide 20.0000%

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-388-6237 ROOM: CS1 6W9

RECEIVED DATE: 04/21/03 DUE OUT DATE: 08/19/03

\* \* \* DATA PACKAGE THEORMATION \* \* \*

DP BARCODE: 290087 EXPEDITE: N DATE SENT: 05/16/03 DATE RET.: / /

CHEMICAL: 000595 Hydrogen peroxide

OP TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 08/19/03
DIV: AD 5/23/23 / NEGOT DATE: 7/5/03
BRAN: PSB 5/23/03 / PROJ DATE: 7/5/03

REVR: // //
CONTR: pyrtup //

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review attached data (MRID #45918801) (Staph & Salmonella) for acceptability.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

FILE SYMBOL/REG NO.					
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REGISTRATION TYP	E: [ ]	CONDITIONA	r [ ]	UNCONDITI	ONAL .
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REVIEW(S) REQUESTED	PACK #	DATE SENT	DUE DATE	Date - Returnes	<u>.</u>
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# TRANSMITTAL DOCUMENT

# 1. NAME AND ADDRESS OF SUBMITTER & SPONSOR

SUBMITTER LAIRD'S REGULATORY CONSULTANTS, INC. **501 SOUTH LINCOLN AVENUE** STERLING, VIRGINIA 20164-2024

**SPONSOR** 

NV CID LINES S.A. WATERPOORTSTRAAT 2 8900 IEPER, BELGIUM

# 2. REGULATORY ACTION TO BE TAKEN

Submission of Additional Efficacy Data

EPA FILE SYMBOL/REG. NO.: 71355-E

PRODUCT NAME: CID 2000 (primary name)/Kickstart (additional name)

# TRANSMITTAL DATE

March 17, 2003

# 3. LIST OF SUMITTED STUDIES

Volume 1: Administrative Materials

ject (02) Volume 2: Efficacy-AOAC Use-Dilution Method, HTR Study #01-109138-11

45885701 Volume 3: Efficacy-AOAC Use-Dilution Method, HTR Study #02-120838-106

45885702 Volume 4: Efficacy-Virucidal Evaluation of Kick-Start Against Avian Reovirus in a Suspension Assay, Project No. 01-7, Biocidal Test #59

458857()3 Volume 5: Efficacy Virucidal Evaluation of Kick-start for Use on Inanimate

Environmental surfaces: Test for Efficacy Against Newcastle Disease

Virus, Project #01-7, Biocidal Test #54

COMPANY OFFICIAL: for

COMPANY CONTACT: OLIVIA D. LAIRD

Phone: (703) 471-6590

FAX: (703) 471-6269

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

CID LINES C/O OLIVIA D. LAIRD 501 SOUTH LINCOLN AVENUE STERLING, VA 20164

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 03/21/03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

# Rejected study [02] :

\* Each study which contains a claim of confidentiality under FIFRA 10(d)(1)(A),(B) or (C) must be prepared with a releasable part of the study as well as a confidential attachment. The releasable part of the study must contain a title page, confidentiality claim statement, any data not protected by the above mentioned FIFRA section and cross reference(s) to protected data which can be found in the confidential attachment. See p. 8 of PR Notice 86-5.





458857-00

To the attention of Marshall Swindell Product Manager 33 Regulatory Management Branch I Antimicrobial Division (7505C)

leper, March 12th, 2003

Dear Mr. Swindell,

Referring to your letter dated Jan 29, 2003 with subject Application for EPA registration CID 2000, we send attached the following documents and comments:

The submitted efficacy data (MRID N° 457670-02) was found to be incorrectly reported.

After contact with Hilltop Research, the laboratory which performed the test, they amended the report to correct the amount of carriers used in the test. Concerning the issue of neutralization control we received following comments from Hilltop:

# Quote:

"With respect to neutralizer effectiveness testing, there is no EPA requirement for neutralizer effectiveness against each organism you test. The requirement is for you to you that your neutralizer has effectively inactivated the antimicrobial in question in the test. The requirement is to either conduct secondary transfers to demonstrate that the antimicrobial effects were overcome or to demonstrate that your subculture medium (AOAC Letheen Broth) was capable of supporting microbial growth after it has been exposed to your test substance (Kickstart).

You fulfilled both of these requirements. ALL testing against all organisms had both primary and secondary transfers with AOAC Letheen Broth. In addition, a neutralization evaluation was conducted (Appendix I of your report) that shows after insulting both the primary and secondary subcultures of Letheen Broth with your product, they were still able to support the growth of bacteria. There is no reason to expect that this would not work equally as well with ":" salmonella choleraesuis as it did with Staphylococcus aureus as the whole purpose of this experiment is to show that the antimicrobial agent has been inactivated prior to the addition of the test organism."

In addition to this amended report we also attached the efficacy reports against Escherichia Coli. Avian Reovirus and Newcastle Disease virus.





Further to the request of the EPA, we also revised the label as per PR Notice 2001-1.

Attached are 5 revised original labels.

Yours sincerely,

Vincent Catry

CID LINES Regulatory Affairs,

This is an ACCEPTED submission

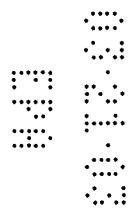
This is a PARTIALLY ACCEPTED/COMPLETELY REJECTED submission

Al-place into PRAT & Return rejected data to Olivia Lairol.
- bive the rest of the pkg to Tony, Cony - check the pathogens c Michelle Wing field My

# **COVER PAGE**

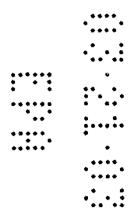
# CID 2000 EPA FILE SYMBOL -71355-E

# ADMINISTRATIVE MATERIALS VOLUME I



# TABLE OF CONTENTS

- 1. Transmittal Document
- 2. Transmittal Letter With Explanation From Lab.
- 3. Five copies of the proposed label



DP BARCODE: D290087

CASE: 069188 DATA PACKAGE RECORD DATE: 05/16/03 SUBMISSION: \$635336 Page 1 of 1

BEAN SHEET

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 189 RESB FQPA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide 20.0000%

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1
PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6B 6W9

RECEIVED DATE: 04/21/03 DUE OUT DATE: 08/19/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 290087 EXPEDITE: N DATE SENT: 05/16/03 DATE RET.: / /

CHEMICAL: 000595 Hydrogen peroxide

P TYPE: 001

CSF: Y ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 08/19/03 NEGOT DATE: / / DIV : AD / / BRAN: PSB PROJ DATE: SECT: EET REVR : CONTR:

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review attached data (MRID #45918801) (Staph & Salmonella) for acceptability.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

BRANCH/SECTION DATE OUT DUE BACK INS CSF DP BC LABEL

# CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 2 9 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Olivia Laird CID Lines c/o Laird's Regulatory Consultants 501 South Lincoln Avenue Sterling, VA 20164-2024

Subject: CID 2000

EPA File Symbol 71355-E

Your Application Dated September 27th, 2002

EPA Received Date October 1st, 2002

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the following reasons:

The submitted efficacy data(MRID No. 457670-02) do not support the use of the product, CID 2000, as a disinfectant with bactericidal activity when tested against Salmonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load(horse scrum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on at least all 10 carriers tested:however, DIS/TSS-1 requires testing of 60 carriers. All three product lots were at least 60 days old at the time of testing. The dried carrier counts were at least at 1x10°. The neutralization confirmation control showed positive growth against Staphylococcus aureus.

Please note: The laboratory may have incorrectly reported the number of carriers tested. The test summary results (page 7 of the MRID) indicated 60 carriers were tested for Salmonella choleraesuis, and test procedures (page 27 of the MRID) called for testing of 60 carriers. However, the Report Form(page 9 of the MRID) indicates that 10 carriers were tested.

The submitted efficacy data (MRID No. 457670-02) do not support the use of the product, CID 2000, as a disinfectant with bactericidal activity when tested against *Pseudomonus aeruginosa* on hard, non-porous surfaces in the persence of a 5% organic soil load(horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a dilution of 1:38 or 1:512. The product was not effective on at least 59 of 60 carriers for the product lots tested.

The submitted efficacy data(MRID No. 457670-03) do not support the use of product, CID 2000, as a disinfectant with bactericidal activity when tested against *Escherichia coli* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:512 dilution. The product was not effective on 10 of 10 carriers for each product lot.

# Acceptable Data

The submitted efficacy data(MRID No. 457670-010)supports the use of the product, CID 2000, as a disinfectant with virueidal activity when tested against *Infectious Bursal Disease* virus(strain D78, ATCC VR-2041) on hard, non-porous hard surfaces in the presence of a 5% organic soil load (fetal bovine serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:384 dilution. Cytoxicity was observed at the 10<sup>-1</sup>to 10<sup>-2</sup> dilutions.

The submitted efficacy data(MRID No. 457670-02) supports the use of the product, CID 2000, with bactericidal activity when tested against Staphylococcus aureus on hard, non-porous surfaces in the presence of a 5% organic soil load(horse serum) and 400 ppm hard surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on least 59 of 60 carriers for each product lot tested. All three product lots were at neutralization evaluation control showed positive growth.

The submitted efficacy data(MRID No. 457670-03) appear to support the use of the product, CID 2000, as a disinfectant with bactericidal activity when tested against *Listeria* monocytogenes, Mycoplasma gallinarum, and Salmonella choleraesuis, serotype enteritidis on hard, non-porous surfaces in the presence of a 5% organic soil load(horse serum) and 400 ppm hard water for a contact time of 10 minutes at 1:512 dilution. The product was not effective on 10 of 10 carriers for each product lot. The dried carrier counts were above 1x104, as required. The neutralization effectiveness control showed positive growth against Mycoplasma gallinarum.

# Labeling

The proposed label claims (as supported by MRID No. 457670-02) are not acceptable regarding the use of the product, CID 2000, as a disinfectant against Samonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. Provide the Agency with a clarification by or from the laboratory as to whether 10 or 60 carriers were tested in this study. If 60 carriers were tested, then provide the Agency additional data that will demonstrate neutralization against Salmonella choleraesuis. If 60 carriers were not tested, then the proposed label claims regarding Salmonella choleraesuis and product use as a "broad spectrum disinfectant" needs to be removed from the label. Adequate and acceptable efficacy data must be generated and submitted for an efficacy determination(refer to item(b)) of DIS/TSS-1 enclosure requirements.

Until adequate and acceptable efficacy data are submitted for a determination against Sabnonella chaleraesuis, the use of the phrase "broad spectrum disinfectant" at the top of page #1 is considered unacceptable. The indicated label comments are applicable for the proposed label, CID 2000, pinpunched 10-01-2002.

However, the proposed label claims are acceptable regarding the use of the product, ClD 2000, as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes.

<u>Organisms</u>	<u>Dilution</u>	MRID No.
Infectious Bursal Disease virus (Strain D78, ATCC VR-20410)	1:384	MRID No. 457670-01
Listeria monocytogenes	1:512	MRID No. 457670-03
Mycoplasma gallinarum	1:512	MRID No. 457670-03
Salmonella choleraesuis	1:512	MRID No. 457670-03
Stapylocoecus aurcus	1:256	MRID No. 457670-02

Revise the First Aid statements as per PR Notice 2001-1.

A complete copy of the science review is enclosed for your records.

The product may not be lawfully distributed in interstate commerce until it is registered.

The Agency reserves a full label review until the above discrepancy have been clarified.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)

# CID 2000

# CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE PEROXYACETIC ACID inert ingredients

26.5% 4.9% 68.6 % 100.0%

# KEEP OUT OF REACH OF CHILDREN

# DANGER

Lawn on Large for End No and Shows torong Statements

# CID 2000 is effective against:

- Bacteria Salmongila Cholerasuis (ATCC 10708) Staphylococcus aureus (ATCC 6538) in a dilution of 1 '256 in 400ppm AOAC synthetic hard water with 5% soil load. Listeria monocytogenes (ATCC 15313), Mycoptasma gallinarum (ATCC 19708), Salmondila Chloreasuis serotype ententidis (ATCC 13076) in a dilution of 1 '512 in 400ppm AOAC synthetic hard water with 5% soil load.
- Virus Infectious Bursal Disease of Chickens TATCC D78 VR-2041). Newcastle Disease (Spales short 539016) and dilution of 1,384 in 400ppm ACAC synthetic hard water with 5% sed load.

EPA Reg. N . 71355-

NET CONTENTS: 1 - 5 gallon(s)

BATCH N . EXPIRY DATE .

EPA Est. Nº /1355-BEL-001

# APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment.

- 1 Farm Equipment and animal housing buildings (potiting & turkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings)
- Halchers Setters, and chick processing facilities.
- Food processing plants (slaughterhouses).
- 4 Trays, racks, carls, chick boxes, cages and other hard audiaces
- S. Trucks and other vehicles
- 6 Votormary trespitate

# FIRST AID STATEMENTS

IF IN EYES. Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention

IF SWALLOWED: Call a doctor or get medical aftention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink premptly a large quantity of milk, egg whites, getatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable murosal damage may contraindicate the use of d



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#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Doniestic Animals

**DANGER** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with snap and water after handling and before eating, drinking, or using tobactor Remove contaminated clothing and wash before rouse.

# PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive Mix only with water. Product must be diluted in accordance with label directions prior to rise. CID 2000 is not combustifile. however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

# **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For quidance contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labelling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard\_non-gorous surfaces: stainless, galvanised and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, 'brick walls, sandwich panels and feeding/drinking equipment:

- A Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and lixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and runse with potable water before reuse.
- E Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals. Its woll as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry
- F Fresh disinfecting solution should be made daily.

# 2. Hatcheries:

Hatchenes: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with scap or detergent. Then rinse with water. Satirate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for Animinutes. Do not house animals or employ equipment until surfaces have been absorbed an indicated. Around disinfecting solution should be made daily or if visibly solled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the months carefully protected. Pro clean surfaces if visibly solled. Disinfect hard, non-porous surfaces, by applying



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CHEST CHESTS AND CONTROL

the disinfecting solution with spray imap, or sponge. All surfaces must remain thoroughly wat for 10 minutes. Allow to air dry. A parable water nose is required for all surfaces that come into contact with tood.

# 4. Trucks and other vehicles:

Clean all vehicles including mots, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

# 5, Veterinary hospitals:

For disinfection of the following hard non-porous surfaces—floors, walls, ceilings, ceunters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove admals and feed from the premises. Clean all surfaces if visibly soiled. Saturate surfaces with the disinfecting solution by using a spray, mop, or springe. Surfaces must remain wet for 10 minutes. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and mose with potable water before reuse. Fresh disinfecting solution should be made daily or if visibly soiled.

## STORAGE AND DISPOSAL:

To not contaminate water, food, or free by storage and disposal

Stgrage. Never return CID 2000 to the original container after it has been retrieved. Avoid all contaminants, especially dirt, Laustic, reducing agents and metals. Contamination and impurities will reduce shell life and can induce decomposition. In case of decomposition, isolate container double container with each water and dilute CID 2000 with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container gut of direct sublight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden patiets.

Procedures for leak of spile. Stop leak if this can be done without risk. Shut off ignition sources and frames, smoking, frares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of posticide. Posticide wastes are assisted that improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency for the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been splited, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rose. Then offer for recycling or puncture and dispose in a sanitary isnotiil. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke

**Note:** This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface of its responsended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

## LIMITED WARRANTY AND DISCLAIMER:

The manufactural warrants (q) mat this product conforms to the chomical description on the tabet (th) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions , and (c) that the directions warrings and of toxicity to bit createry accords. These have not been made on all various or in all states or under all engages of effectiveness and of toxicity to bit createry accords. These have not been made on all various or in all states in under all engages of the manufacturer neither makes not intends not cools it authorize any agent or representative to make, any other warranties, organised or implied, and it expressly excludes and disclaims all implied warranties in meritain being and forces for particular compose. This warranty opens not extend to, and the buyer shall be solely responsible for, any and all loss or carrage when resulting from the use of this product was also as in sections when the faller threshold it forces contained regional or influence and discovery and all claims haves a product or explicit or influence of otherwise or changing in if this product, whether the expectation is replaced in the containt replacement of the purchase pure for the quarter of product with respect to which obscious and contains a containing and the containing and the special indicators of the containing and the containing an



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# CID 2000

# CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE PEROXYACETIC ACID

mert ingredients

26.5% 4 9% 9/4 Q 3. uni n

# KEEP OUT OF REACH OF CHILDREN

# DANGER

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# CID 2000 is effective against:

- Bacteria: Salmonella Cholerasus (ATCC 10708), Staphylococcus aureus (ATCC 6538) in a dilution of 1, 256 in 400ppm AOAC synthetic hard water with 5% soll load. Listeria monocytogenes (ATCC 15313). Mycopiasma gellinarum (ATCC 19708), Salmonolla Chloreasuis sorotype enteritidis (ATCC 13076) in a dilution of 1-512 in 400ppm AOAC synthetic hard water with 5% soil load
- Virus Infortious Bursat Dispaso of Checkens, (ATCC D76 VR-2041), Newcastlo Disease (Spafas strain 539016), in a dilution of 1, 384 in 400ppn) ACIAC synthetic hald water with 5% soil load.

EPA Reg N /1365

NET CONTENTS 1 Syationics

BATCHIN EXPIRY DATE

EPA Est N . 71365 BEL 001

APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment

- 1 Farm Equipment and animal housing buildings (poullry & furkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings).
- 2 Hatchers Setters, and chick processing facilities
- Food processing plants (staughterhouses).
- Trays, racks, carts, chick boxes, cages and other hard surfaces
- 5. Trucks and other vehicles.
- 6 Vetergary hospitals

# FIRST AID STATEMENTS

IF IN EYES. Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN. Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention

IF SWALLOWED Call a dector or get medical attention. Do not induce verniting or give anything by. mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gefatin solution, or if those are not available, grink large quantities of water. Avoid alcohol-

NOTE TO PHYSICIAN. Probable precessf demands may contrandicate the use of our



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#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER**, CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubbor gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse

#### PHYSICAL AND CHEMICAL HAZARDS

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. CID 2000 is not combustible; however, at temperatures exceeding 150°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

# **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, pends, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labelling,

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces; stainless, galvanised and painted steel, copper, atuminum, finished wood, vinyl, plastics, glazed tiles, brick walls, sandwich panels and feeding/drinking equipment;

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manufe from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B Thoroughty clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilete buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, froughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry
- F Fresh distrifecting solution should be made darly

# 2. Hatcheries :

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing lables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or it visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all lood products and packaging materials must be removed from the reomic carefully protected. Pre-clean surfaces if visibly soiled. Disinfect thard, fron-porous surfaces by applying



NV CID LINES SA - Waterpoortstraat 2 8900 IEPER - BELCIUM - ELIROPE 191 011 32 57 217877 18X 011 32 57 217879 4-102 - Ordons (Collings No. the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food

# 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfection solution wet for 10 minutes. Allow to air dry.

# 5. Veterinary hospitals:

For disinfection of the following hard non-porous surfaces; floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Clean all surfaces if visibly soiled. Saturate surfaces with the disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly sorub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfecting solution should be made daily or if visibly soiled.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Nover return CiD 2000 to the original container after it has been removed. Avoid all contaminants, especially dirf, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with coel water and dilute CID 2000 with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use, Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden paliets

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water, Undiluted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are nortely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may very by location, regulatory agencies should be confacted by prior to disposal. CfD 2000, which is to discharged, should be disposed of as hazardous waste ofter contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a samlary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning, if burned, stay out of smoke.

**Note:** This product at its use dilution is compatible with stanfess stept and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

# LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label (b) that this product is a reaconable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrants and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of boxicity to laboratory animals. Easts have not been made or all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor cook it sufficient any agent or representative to make, any other warrantees expressed or implied, and if expressly excludes and disclaims all indifes warranties or merchantability and fitness for particular purposes. This warranty does not extend to, and the buyer shall be solely responsible for any and all loss or damage which results now the use of this product in any manufacturer's or netter's exclusive liability for any and all claims, forces, admages, or injuries resulting from the use or handlang of this product, whether or not such liability is based in the contract, negligened, sinci liability is that of otherwise, shall be limited, at the manufacturer's uption, to replacement of, or the repayment of the purchase report, indirect or consecuential damages are claimed, in no exact onal manufacturer or setter be upter for execut, indirect or consecuential damages mageing from the use or handling of this product.



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# CID 2000

# CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients 26.5% 4.9% 68.6 % 100.0%

# KEEP OUT OF REACH OF CHILDREN

# DANGER

See sice panel for first Aid and Precedimentry Statements.

# CID 2000 is effective against:

- Bacteria: Salmonella Cholorasuis (A1CC 10708), Staphylococcus aureus (A1CC 6538) in a dilution of 1:256 in 400ppm AOAC synthetic hard water with 5% soit toad. Listeria monocylogenes (ATCC 15313), Mycoplasma gaillnarum (ATCC 19708), Salmonella Chioreasuis serotype enteritidis (ATCC 13076) in a dilution of 1:512 in 400ppm AOAC synthetic hard water with 5% soit toad.
- Virus : Infections Bursat Disease of Chickens (ATCC D78.VR-2041). Newcastle Disease (Spafas strain 539016) in a dilution of 1-384 in 400ppm AQAC synthetic hard water with 5% soil lead.

EPA Reg. N° : 71355

NET CONTENTS 1 5 gallon(s)

BATCH N°

EPA Est. Nº 71355-BEL-001

EXPIRY DATE .

# APPLICATION:

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

- Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large, animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3. Food processing plants (slanghterhouses)
- 4. Trays, racks, carts, chick boxes, cages and other hard surfaces
- 5. Trucks and other vehicles.
- 6 Veterinary hospitals

## FIRST AID STATEMENTS

IF IN EYES Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, getatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of of



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# PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

# PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. CID 2000 is not combustible, however, at temperatures exceeding 156°F decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

## **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sawer systems without previously notifying the local sawage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labelling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-parous surfaces: stainless, galvanised and painted steel, copper, altiminum, finished wood, vinyl, plastics, glazed tiles, brick walls, sandwich panels and feeding/drinking equipment.

- A. Remove all animals and feed from promises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chules, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with polable water before reuso.
- E Disinfection of equipment. Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing titler and manurum the disinfecting solution for 10 minutes. Allow to air day.
- F. Fresh disinfecting solution should be made daily

# 2. Hatcheries :

Hatchones: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain well or 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. From disinfecting solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the coom or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-perous surfaces by applying



NV CID LINES SA - Waterpsonsmaat 2 8900 IEPER - 8ELGIUM - EUROPE 141 1) 11 32 57 21/1877 13x 011 32 37 21/1878 2-mat - college@cidenes.bp the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

# 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

# 5. Veterinary hospitals:

For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Clean all surfaces if visibly soiled. Saturate surfaces with the disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfecting solution should be made daily or if visibly soiled.

# STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Never return CID 2000 to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shell life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute CID 2000 with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for leak of spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

## LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the tabel; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this tabel are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the tabel directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, tosses, gardings, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be liabiled, at the manufacturer's option, to replacement of, or the repayment of the purchase arice for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be fiable for special, indirect or consequential damages resulting from the use or handling of this product.



NV CID LINES SA - Waterpoortstraat 2 9900 IEPER - BELGIUM - EUROPE Iel. 011 32 57 217877 fax 011 32 67 21/8/6

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### **CID 2000**

#### CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients:

HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients

26.5% 4.9% 68.6 % 100.0%

#### KEEP OUT OF REACH OF CHILDREN

#### DANGER

See side panel for First Aid and Precautionary Statements.

#### CID 2000 is effective against:

- Bacteria: Salmonella Cholerasuis (ATCC 10708), Staphylococcus aureus (ATCC 6538) in a dilution of 1:256 in 400ppm AOAC synthetic hard water with 5% soil load. Listeria monocytogenes (ATCC 15313), Mycoplasma gallinarum (ATCC 19708), Salmonella Chloreasuis serotype enteritidis (ATCC 13076) in a dilution of 1:512 in 400ppm AOAC synthetic hard water with 5% soil load
- Virus: Infectious Bursal Disease of Chickens (ATCC D78, VR-2041), Newcastle Disease (Spafas strain 539016) in a dilution of 1:384 in 400ppm AOAC synthetic hard water with 5% soil load

EPA Reg. N": 71355-

NET CONTENTS : 1 - 5 gallon(s)

BATCH N°:

EPA Est. N°: 71355-BEL-001

EXPIRY DATE:

#### **APPLICATION:**

Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

- 1. Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3. Food processing plants (slaughterhouses)
- 4. Trays, racks, carts, chick boxes, cages and other hard surfaces
- 5. Trucks and other vehicles
- 6. Veterinary hospitals.

#### FIRST AID STATEMENTS

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical allention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of castge javage.



NV CID LINES SA - Waterpoortstraat 2 8900 IEPER - BELGIUM - EUROPE tot. 011 32 57 217877 fax 011 32 57 217879 e-mail . cidlines@cidlines.be

#### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

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#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labelling.

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces: stainless, galvanised and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tites, brick walls, sandwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, waits and surfaces of barns, pens, stalls, chules, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with disinfecting solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the disinfecting solution for 10 minutes. Allow to air dry.
- F. Fresh disinfecting solution should be made daily.

#### 2. Hatcheries :

Hatcheries: Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfecting solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Pre-clean surfaces if visibly soiled. Disinfect hard, non-porous surfaces by applying



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e-mail: <u>cidlines@cidlines.be</u>

the disinfecting solution with spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

#### 4. Trucks and other vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the disinfecting solution to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

#### 5. Veterinary hospitals:

For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Clean all surfaces if visibly soiled. Saturate surfaces with the disinfecting solution by using a spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfecting solution should be made daily or if visibly soiled.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposat

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Procedures for leak of spill: Stop teak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undituted material should not enter confined spaces.

Disposat of pesticide: Pesticide wastes are acutely hazardous, tmproper disposat of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to tabel instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If materiat has been spilled, an acceptable method of disposal is to dilute with at teast 20 volumes of water followed by discharge into suitable treatment system in accordance with all tocal, slate, and Federal environmental laws, rutes, regulations, standards, and other regulrements. Because acceptable methods may vary by location, regulatory agencies should be contacted by prior to disposal. CIO 2000, which is to discharged, should be disposed of as hazardous waste after contacting the appropriate tocal, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse, Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**Note:** This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, o expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which fastilis from the use of this product in any manner which is inconsistent with the label directions, warrings or cauties.

Buyer's exclusive remedy and manufacturer's or sellar's exclusive liability for any and all claims, losses, gamages, or injuries, resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.



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e-mail : <u>cidlines@cidlines.be</u>



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

January 22, 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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#### **MEMORANDUM**

Subject:

Secondary Review of Contractor's (DynCorp Systems & Solutions LLC)

Efficacy Review of CID 2000,

EPA Reg. No. 71355-E.

Case No. 069188 DP Barcode: D286206

From:

Bruce H. Mann

Efficacy Evaluation Team

Product Science Branch (7510C)

To:

Marshall Swindell, PM 33/Karen Leavy-Munk

Regulatory Management Team II Antimicrobials Division (7510C)

Thru:

Emily Mitchell, M.S., Team Leader Thuly With Lell 1/25/63
Efficacy Evaluation

Efficacy Evaluation

Antimicrobials Division (7510C)

Applicant:

NV CID LINES® SA

8900 leper, Belgium

#### Formulation Label:

Active Ingredient(s)	<u>% by wt.</u>
Hydrogen peroxide	
Peroxyacetic acid	
Inert Ingredient(s)	
Total	

#### 1 BACKGROUND

The product, CID 2000 (EPA Reg. No. 71355-E), is a new product. The applicant requested to register the product as a broad spectrum disinfectant and virucide for use on hard, non-porous, non-food contact surfaces on farms and in veterinary hospitals and food processing plants. The label claims that the product is effective in the presence of a 5% organic soil load. Studies were conducted at Southern Microbiology Associates, LLC located at 4204 Edmonton Drive in Bessemer, Alabama 35022; and Hill Top Research, Inc. located on Main and Mill Streets in Miamiville, Ohlo 45147.

This data package contained EPA Form 8570-4 (Confidential Statement of Formula), three studies (MRID Nos. 457670-01 through 457670-03), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

Note: Correspondence from the applicant states that CID 2000 (primary name) and Kickstart (additional name) are "identical products towards chemical composition."

Note: The data package included a label for the acid-based sanitizer, CID 2000 (dated-stamped September 12, 2000 by EPA), and a label for the disinfectant, CID 2000 (date-stamped October 1, 2002 by EPA). The formulations for the two products are slightly different. The label for the acid-based sanitizer, CID 2000, appears to be irrelevant to the data package and may be a previous draft of the product label.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

#### II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as buildings, floors, walls, ceilings, counters, animal pens/cages, vehicle items (e.g., mats, crates, cabs, wheels); feeding/drinking equipment, and handling/restraining equipment. Directions on the proposed label provided the following Information regarding preparation and use of the product as a disinfectant: Prepare use solution by mixing an appropriate amount of the product with water (1:256 to treat against Salmonella choleraesuis, Staphylococcus aureus; 1:512 to treat against Listeria monocytogenes, Mycopiasma gallinarum, and Salmonella choleraesuis serotype enteritidis; and 1:384 to treat against Infectious Bursal Disease virus and Newcastle Disease virus). Remove all animals and feed from the area. Remove all litter and manure from floors, walls, and surfaces. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with use solution by using spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried. Before reuse, thoroughly scrub treated feeding and watering appliances with soap or detergent and rinse with potable water. Disinfect equipment by immersing equipment in use solution for 10 minutes. Allow to air dry. Fresh disinfecting solution should be made daily.

#### AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

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The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 104 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Microorganisms)

The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis (ATCC 10708) and Staphylococcus aureus (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different batches. To support products labeled as "disinfectants" for specific microorganisms (other than those microorganisms named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10<sup>4</sup> microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are presented in DIS/TSS-2.

#### IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 457670-01 "Virucidal Evaluation of Kick-Start for Use on Inanimate Environmental Surfaces: Test for Efficacy Against Infectious Bursal Disease Virus," by Hazel R. Bowdon. Study conducted at Southern Microbiology Associates, LLC. Study completion date — May 23, 2002.

This study was conducted against Infectious Bursal Disease virus (Strain D78, ATCC VR-2041), using chick embryo fibroblasts as the host system (source of host not indicated). Two lots (Lot Nos. 104760 and 200260) of the product, Kickstart, were tested according to the EPA Pesticide Assessment Guidelines, 1982. A use solution was prepared by diluting 1 mL of the product in 38.3 mL of 402.5 ppm hard water (a 1:384 dilution). The stock virus titer contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over approximately 23 to 28 cm² on the bottoms of sterile glass Petri dishes. The virus films were air-dried at 20-25°C for 20-45 mlnutes. For each lot of product, virus films were exposed to 2.0 mL of the use solution at 23°C. The exposure was terminated after 9.5 minutes by passage through Sephadex gel columns. This procedure lasted approximately 30 seconds, which increased the exposure to 10 minutes. The Sephadex filtered solutions were diluted serially in 1-log dilutions. Each serial dilution was added in a 0.2 mL quantity to each of 4 wells of chick embryo fibroblasts. Controls included cytotoxicity and neutralization. Viral and cytotoxicity titers were calculated by the Reed and Muench method (1938).

2. MRID 457670-02 "AOAC Use-Dilution Method" for Kickstart, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – November 20, 2001

This study was conducted against Staphylococcus aureus (ATCC 6538), Salmonella choleraesuis (ATCC 10708), and Pseudomonas aeruginosa (ATCC 15442). Three lots (Lot Nos. 101760, 102360, and 102960) of the product, Kickstart, were tested using the AOAC Use-Dilution Method, as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was tested in the presence of a 5% organic soil load (horse serum). All product lots were at least 60 days old at the time of testing with one exception; it is unconfirmed whether at least one of the product lots tested against Pseudomonas aeruginosa (at a 1:512 dilution) was at least 60 days old at the time of testing. A 1:256 dilution of the product (using 400±10 ppm AOAC synthetic hard water (titrated value not indicated)) was tested against Staphylococcus aureus and Salmonella choleraesuis. A 1:384 and 1:512 dilution of the product (using 400±10 ppm AOAC synthetic hard water (titrated value not indicated)) was tested

against *Pseudomonas aerugi*nosa. Polished stainless steel cylinder carriers were immersed for 15 minutes in 10 mL of a 48-54 hour old suspension of the test organism. The carriers then were dried for 40 minutes at 37±1°C. The carriers were exposed to 10 mL of the use solution for 10 minutes at 20±1°C. After exposure, the carriers were transferred into tubes containing 10 mL of Letheen Broth. After 30 minutes, the carriers were subcultured again into tubes containing Letheen Broth. All tubes were incubated at 37±1°C for 48±2 hours. Following incubation, the tubes were observed for growth or no growth. Controls included phenol resistance, neutralization evaluation, cytotoxicity, and dried carrier counts.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 457670-03 "AOAC Use-Dilution Method" for Kickstart, by Kathleen A. Baxter. Study conducted at Hill Top Research, Incorporated. Study completion date – February 1, 2002.

This study was conducted against Escherichia coli (ATCC 11229), Listeria monocytogenes (ATCC 15313), Mycoplasma gallinarum (ATCC 19708), and Salmonella choleraesuis, serotype enteritidis (ATCC 13076). Two lots (Lot Nos. 101760 and 102360) of the product, Kickstart, were tested using the AOAC Use-Dilution Method, as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was tested at a 1:512 dilution in 400±10 ppm AOAC synthetic hard water (titrated value not indicated) in the presence of a 5% organic soil load (horse serum). Ten polished stainless steel cylinder carriers were immersed for 15 minutes in 10 mL of a suspension of the test organism. The carriers then were dried for 40 minutes at 37±1°C. The carriers were exposed to 10 mL of the use solution for 10 minutes at 20±1°C. After exposure, the carriers were transferred into tubes containing 10 mL of Letheen Broth (for Escherichia coli and Salmonella choleraesuis, serotype enteritidis), Brain Heart Infusion Broth (for Listeria monocytogenes), or Mycoplasm Medium (for Mycoplasma gallinarum). After 30 minutes, the carriers were subcultured again into tubes containing neutralizing medium. All tubes were incubated at 37±1°C for 48±2 hours except tubes containing Mycoplasma gallinarum which were incubated at 37±1°C with 5% CO<sub>2</sub> for 48±2 hours. Following incubation, the tubes were observed for growth or no growth. Controls included phenol resistance, neutralization evaluation, cytotoxicity, and dried carrier counts.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID	Organism		Dried Virus Control		
			Lot No. 104760	Lot No. 200260	(TCID <sub>50</sub> /0.2 mL)
457670-01 Infectious Bursal Disease virus (Strain D78, VR- 2041)		10 <sup>-1</sup> and 10 <sup>-2</sup> dilution	Cytotoxicity present	Cytotoxicity present	5.5
	virus	10 <sup>-3</sup> to 10 <sup>-6</sup> dilution	Complete inactivation	Complete inactivation	
	TCID <sub>so</sub> /0.2 mL	≤2.5	≤2.5		
		Log reduction	≥3.0	≥3.0	

MRID Number	Organism	No. Exhi	Dried Carrier Count		
		Lot No. 101760	Lot No. 102360	Lot No. 102960	(CFU/carrier)
457670- 02	Staphylococcus aureus	1° - 1/60 2° - 0/60	1° - 0/60 2° - 0/60	1° - 0/60 2° - 0/60	7.4 x 10 <sup>6</sup>
457670- 02	Pseudomonas aeruginosa 1:512 in 400 ppm	1° - 2/60 2° - 3/60	1" - 1/60 2° - 3/60	1° - 2/60 2° - 2/60	5,2 x 10 <sup>6</sup>
	1:384 in 405 ppm	1° - 1/60 2° - 2/60	1° - 1/60 2° - 1/60	1° - 0/60 2° - 3/60	8.2 x 10 <sup>8</sup>
457670- 02	Salmonella choleraesuis	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1.3 x 10 <sup>6</sup>

MRID Number	Organism	No. Exhibiting No. T	Dried Carrier Count	
			Lot No. 102360	(CFU/carrier)
457670-03	Escherichia coli	1° - 10/10 2° - 10/10	1° - 10/10 2° - 10/10	2.2 × 10 <sup>7</sup>
	Listeria monocytogenes	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1.6 x 10 <sup>6</sup>
	Mycoplasma gallinarum	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	6.8 x 10 <sup>5</sup>
	Salmonella choleraesuis, serotype enteritidis	1° - 0/10 2° - 0/10	1° - 0/10 2° - 0/10	1.5 × 10 <sup>6</sup>

#### VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 457670-01) support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with virucidal activity when tested against Infectious Bursal Disease virus (Strain D78, ATCC VR-2041) on hard, non-porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:384 dilution. Cytotoxicity was observed at the 10<sup>-1</sup> to 10<sup>-2</sup> dilutions. Complete inactivation (no growth) was observed in the 10<sup>-3</sup> to 10<sup>-6</sup> dilutions. A 3-log reduction in titer was demonstrated beyond the cytotoxic level. The recoverable virus titer was at least 10<sup>4</sup>.

- 2. The submitted efficacy data (MRID No. 457670-02) support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Staphylococcus aureus* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on at least 59 of 60 carriers for each product lot tested. All three product lots were at least 60 days old at the time of testing. The dried carrier counts were at least 1 x 10<sup>4</sup>. The neutralization evaluation control showed positive growth.
- 3. The submitted efficacy data (MRID No. 457670-02) do not support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Salmonella choleraesuis* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a 1:256 dilution. The product was effective on at least all 10 carriers tested; however, DIS/TSS-1 requires testing of 60 carriers. All three product lots were at least 60 days old at the time of testing. The dried carrier counts were at least 1 x 10<sup>4</sup>. The neutralization confirmation control showed positive growth against *Staphylococcus aureus*.

Note: The laboratory may have incorrectly reported the number of carriers tested. The test summary results [page 7 of the MRID] indicated 60 carriers were tested for Salmonella choleraesuis, and test procedures [page 27 of the MRID] called for testing of 60 carriers. However, the Report Form [page 9 of the MRID] indicates that 10 carriers were tested.

- 4. The submitted efficacy data (MRID No. 457670-02) do not support the use of the product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Pseudomonas aeruginosa* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water surfaces for a contact time of 10 minutes at a dilution of 1:384 or 1:512. The product was not effective on at least 59 of 60 carriers for the product lots tested.
- 5. The submitted efficacy data (MRID No. 457670-03) appear to support the use of the product, CID 2000 (primary name) or Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Listeria monocytogenes*, *Mycoplasma gallinarum*, and *Salmonella choleraesuis*, serotype *enteritidis* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:512 dilution. The product was effective on 10 of 10 carriers for each product lot tested. The dried carrier counts were above 1 x 10<sup>4</sup>, as required. The neutralization effectiveness control showed positive growth against *Mycoplasma gallinarum*.
- 6. The submitted efficacy data (MRID No. 457670-03) <u>do not support</u> the use of product, CID 2000 (primary name) and Kickstart (additional name), as a disinfectant with bactericidal activity when tested against *Escherichia coli* on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) and 400 ppm hard water for a contact time of 10 minutes at a 1:512 dilution. The product was not effective on 10 of 10 carriers for each product lot.

#### VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, CID 2002 (primary name) and Kickstart (additional name), as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes:

<u>Organisms</u>	Dilution	MRID No.
Infectious Bursal Disease virus		
(Strain D78, ATCC VR-2041)	1:384	MRID No. 457670-01
Listeria monocytogenes	1:512	MRID No. 457670-03
Mycoplasma gallinarum	1:512	MRID No. 457670-03
Salmonella choleraesuis, serotype enteritidis	1:512	MRID No. 457670-03
Staphylococcus aureus	1:256	MRID No. 457670-02

2. The proposed label claims (as supported by MRID No. 457670-02) are not acceptable regarding the use of the product, CID 2002 (primary name) and Kickstart (additional name), as a disinfectant against Salmonella choleraesuis on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a contact time of 10 minutes at a 1:256 dilution. The applicant needs to provide the Agency with a clarification by or from the laboratory as to whether 10 or 60 carriers were tested in this study. If 60 carriers were tested, then, the applicant needs to provide the Agency additional data that will demonstrate neutralization against Salmonella choleraesuis. If 60 carriers were not tested, then proposed label claims regarding Salmonella choleraesuis and product use as a broad-spectrum disinfectant need to be removed from the label. Adequate and acceptable efficacy must be generated and submitted for an efficacy determination (refer to item (b) of DIS/TSS-1 enclosure for efficacy requirements).

Until adequate efficacy data are submitted for a determination against Salmonella choleraesuis, the use of the phrase 'broad spectrum disinfectant" at the top of page #1 is considered unacceptable. The indicated label comments are applicable for the proposed label "CID 2000" pinpunched 10-01-2002.

- 3. Efficacy data submitted for the following microorganisms do not support effectiveness of the product at a 10 minute contact time in the presence of a 5% organic soil load. Eventhough, the proposed label does not include label claims for these microorganisms, a listing of the proposed test microorganisms is considered unacceptable. Until adequate efficacy data are submitted in support of effectiveness against *Pseudomonas aeruginosa*, the proposed label claim for veterinary hospitals is considered unacceptable. The comment is applicable for page #3 on the proposed label "CID 2000" pinpunched 10-01-2002.
- Pseudomonas aeruginosa, as supported by MRID No. 457670-02
- Escherichia coli, as supported by MRID No. 457670-03
- 4. The proposed label includes claims of product efficacy against Newcastle Disease virus at a 1:384 dilution. The submitted data package provided to the Agency do not include any efficacy studies in support of this proposed label claim. Therefore, the proposed label claim against the

microorganism, New Castle Disease virus, is unacceptable and must be removed from the product proposed label "CID 2000", pinpunched 10-01-2002.

5. Until the applicant submit adequate and acceptable efficacy data in support of a usage for veterinary hospitals and a use as a broad spectrum disinfectant, the product proposed label "CID 2002" is considered unacceptable.

E128

#### TASK ASSIGNMENT FORM(TAF)

Antimicrobial Division/OPP--Effective June 5, 1998

PO: Zenobia Jones A -- Completed by Reviewer/Team Leader (check(√) or complete appropriate boxes) **Product Toxicology** Human Toxicology\_ **Product Chemistry** Efficacy X PSB X RASSB DP Barcode: D286206 Chemical: Hydrogen peroxide Lit. Search\_ FQPA X Type: Registration RED Prod. Reregistration Special Project Other \_ Due Date: 12/16/02 AD Contact: **Emily Mitchell** Team Leader: Emily Mitchell Completed by Reviewer/Team Leader C - Completed By Contractor MRID GDLN# Gov't Est Hrs Study/Action Tech Hrs. Spent Virucidal Evaluation of Kick-Start for Use on Inanmate 457670-01 91-2 5 Environmental Surfaces: Test for Efficacy Against Infectious **Bursal Disease Virus** OAC Use-Dilution Method 457670-02 91-2 5 AOAC Use-Dilution Method 457670-03 91-2 5 Review Instructions/Comments

See attached page\_

- Completed by WAM	A/PO				
Action No: E128	Date Sent:		WAM/PO:	Branch Chief (For	r Special Projects);
E - Completed by Contr.	actor				
Date Delivered:	Delivery:	Fed Ex_	Courier_	Electronic_	Other_
Principal Reviewers:					
leges/Comments for Secon	ndary Reviewer	Attention:			See attached page_
F - Completed by Secon	dary Reviewer	(Antimicrobial )	Division)		
Minor Changes/Resolution	with Contractor		Major Changes/Resolution	with Contractor	
Secondary Review Hours_		Accepted_	Unacce	ptable	
viewer Comments Recor	mmendations:				See attached page

CASE: 069188 DATA PACKAGE RECORD DATE: 10/28/02 SUBMISSION: S623448 BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 189 RESB FOPA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide 20.0000\$

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9

RECEIVED DATE: 10/01/02 DUE OUT DATE: 01/29/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 286206 EXPEDITE: N DATE SENT: 10/16/02 DATE RET.: / /

HEMICAL: 000595 Hydrogen peroxide

P TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 01/19/03
DIV: AD 10/24/02 // NEGOT DATE: 12/29/02
BRAN: PSB 10/24/02 // PROJ DATE: 12/15/02
SECT: IO 10/24/02 //
REVR: VMIDDLET // //

REVR: VMIDDLET / / / / / / / / / / / / / / CONTR: DYNCORP 10/28/02 / /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the Efficacy Data to support labeling claims (457670-01; -02 and -03).

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

TASK ASSIGNMENT FORM(TAF)
Antimicrobial Division/OPP--Effective June 5, 1998

PO: Zenobia Jones

A Completed by Reviewer/Team Leader (check(√) or complete appropriate boxes)						
RASSB	PSBX_	Product Toxicology	Human Toxicology_	Product	Chemistry	Efficacy <u>X</u>
Chemical: Hydi	rogen peroxide			DP Bar	code: D286206	
Type: Registratio	n_ RED_ Pr	nd. Reregistration_ PQPA	X Special Project_	Lit. Scarch_	Other	
Due Date: 12/16/	/02 AD Con	tact: Emily Mitchell		Team L	eader: Emily Mito	hell
Completed by	y Reviewer/Team	Leader				C - Completed By Contractor
	Study/Actio	on	MRID	GDLN#	Gov't Est Hrs	Tech Hrs. Spent
Virucidal Evaluation of Kick-Start for Use on Inanmate Environmental Surfaces: Test for Efficacy Against Infectious Bursal Disease Virus			457670-01	91-2	5	
AOAC Use-Dilutio	on Method		457670-02	91-2	5	
AOAC Use-Dilutio	on Method		457670-03	91-2	5	
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Review Instructions/Comments  See attached page						

D Completed by W	AM/PO				
Action No: E128	Date Sent:		WAM/PO;	Branch Chief (Fo	r Special Projects):
E Completed by Co	ntractor				
Date Delivered:	Delivery:	Fed Ex_	Courier_	Electronic_	Other_
Principal Reviewers:					
es/Comments for Se	econdary Reviewer	Attention:			
					See attached page_
F Completed by Sec	condary Reviewer	(Antimicrobial Di	vision)		
Minor Changes/Resolut	tion with Contracto	r	Major Changes/Resolution	with Contractor	
Secondary Review Hou	rs	Accepted	Unacce	ptable	
Reviewer Comments Re	ecommendations:				See attached page

CASE: 069188 DATA PACKAGE RECORD DATE: 10/28/02

SUBMISSION: S623448 BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 189 RESB FQPA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide 20.0000%

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9

RECEIVED DATE: 10/01/02 DUE OUT DATE: 01/29/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 286206 EXPEDITE: N DATE SENT: 10/16/02 DATE RET.: / /

HEMICAL: 000595 Hydrogen peroxide

P TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 01/19/03
DIV: AD 10/24/02 // NEGOT DATE: 12/29/02
BRAN: PSB 10/24/02 // PROJ DATE: 12/15/02
SECT: IO 10/24/02 //

REVR: VMIDDLET / / / / / / / / / / / / CONTR: DYNCORP 10/28/02 / /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the Efficacy Data to support labeling claims (457670-01; -02 and -03).

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

CASE: 069188 SUBMISSION: S623448 DATA PACKAGE RECORD

BEAN SHEET

DATE: 10/16/02 Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION

ACTION: 189 RESB FQPA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide

20.0000%

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9

RECEIVED DATE: 10/01/02 DUE OUT DATE: 01/29/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 286206 EXPEDITE: N DATE SENT: 10/16/02 DATE RET.: / /

CHEMICAL: 000595 Hydrogen peroxide

PP TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 01/19/03

DIV: AD /// NEGOT DATE: //

BRAN: PSB /// // PROJ DATE: //

BRAN: PSB / / / / / SECT: EET / / / / / REVR: / / / / CONTR: / / / /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the Efficacy Data to support labeling claims (457670-01; -02 and -03).

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

CASE: 069188 DATA PACKAGE RECORD DATE: 10/16/02

SUBMISSION: S623448 BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 189 RESB FQPA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide 20.0000%

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9

RECEIVED DATE: 10/01/02 DUE OUT DATE: 01/29/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 286206 EXPEDITE: N DATE SENT: 10/16/02 DATE RET.: / /

CHEMICAL: 000595 Hydrogen peroxide

TYPE: 001

CSF: Y LABEL: Y

DATE DATE OUT ASSIGNED TO INADMIN DUE DATE: 01/19/03 DIV : AD 10/24/02 NEGOT DATE: /2/29/02 BRAN: PSB 10/24/02 PROJ DATE: 12/15/02 SECT: EET

10/24/02 REVR :

CONTR: Spilly

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the Efficacy Data to support labeling claims (457670-01; -02 and -03).

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL DP BC

# Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

457670-00

September 27, 2002

Mr. Marshall Swindell, PM 33 Environmental Protection Agency Regulatory Management Antimicrobial Division (7510C) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

Subject: CID 2000

**EPA FILE SYMBOL 71355-E** 

Submission of additional data to support registration

Dear Mr. Swindell:

Attached hereto please find five (5) copies of the revised labeling containing our proposed uses along with the letter of authorization form our supplier to address your chemistry data concerns. Also included with this package are the supportive efficacy data which will address efficacy concerns for the product referenced. Additional data are still underway and will be submitted after upon completion.

Please note, the efficacy date was conducted on what is potentially one of our additional brand names for this product. Rest assured that the formula is the same. Letter from the registrant is attached to the study as well to address any concerns you or the reviewers may have concerning the name on the study.

Thank you for your help in this matter. Should you have any questions or concerns please don't hesitate to let me know.

Sincerely,

Olivia D. Laird President/Agent

#### TRANSMITTAL DOCUMENT

#### 1. NAME AND ADDRESS OF SUBMITTER & SPONSOR

SUBMITTER
LAIRD'S REGULATORY CONSULTANTS, INC.
501 SOUTH LINCOLN AVENUE
STERLING, VIRGINIA 20164-2024

**SPONSOR** 

NV CID LINES S.A. WATERPOORTSTRAAT 2 8900 IEPER, BELGIUM

#### 2. REGULATORY ACTION TO BE TAKEN

Submission of Additional Efficacy Data

EPA FILE SYMBOL/REG. NO.: 71355-E

PRODUCT NAME: CID 2000(primary name)/Kickstart(additional name)

TRANSMITTAL DATE

September 27, 2002

3. LIST OF SUMITTED STUDIES

Volume 1: Administrative Materials

45767001Volume 2: Efficacy-against infectious bursal disease virus 45767002Volume 3: Efficacy-AOAC Use Dilution, study #01-109138-11

45767003 Volume 4: Efficacy-AOAC Use Dilution, Study #01-109139-11

COMPANY OFFICIAL: 10t VINCENT CATRY

COMPANY CONTACT: OLIVIA D. LAIRD

Phone: (703) 471-6590

FAX: (703) 471-6269

yol. 2

Marian disease

186





To the attention of Marshall Swindell Product Manager 33 Regulatory Management Branch I Antimicrobial Division (7505C)

leper, sept 24, 2002,

Dear Mr. Swindell,

We would like to confirm that CID 2000 and KICKSTART are identical products towards chemical composition. CID 2000 is currently pending for registration under file number 71355-E.

All efficacy reports however (by Hilltop Research and SMA) are made under the name of KICKSTART.

In a second stage we will differentiate the two products, as they will be assigned different applications.

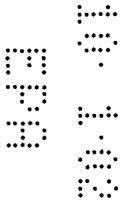
Yours sincerely,

Vincent Catry
CID LINES Regulatory Affairs,

Waterpoonstraat 2 8900 (EPER - Belgium 7 - \$20 (-3) 78 77 - Fax - 32(0)57 21 78 79

#### TABLE OF CONTENTS

- 1. Transmittal Document
- 2. Tansmittal Letter
- 3. Letter of reference from Degussa on chemistry4. Five copies of the revised label



### degussa.

Vincent Catry Cld Lines NV Waterpoortstraat 2 B-8900 leper

Belgium

**Degussa Corporation** 

379 Interpace Parkway P.O. Box 677 Parsippany, NJ 07054-0677

Direct: (973) 541-8053 Fax: (973) 541-8040

Kathleen,Nese@degussa.com www.degussa.com

Dear Mr. Catry,

Degussa Corporation has received your request to be allowed to cite Product Chemistry data used by Degussa in the FIFRA registration of Peraclean 5. The number assigned to the report in which this data is contained is MRID 44506501. Degussa Corporation does not seek any compensation for your use of this data.

I recommend that you include a copy of this letter with your product registration documentation and associate this document with your data matrix, EPA Form 8570-35.

Best regards,

Kathleen Nese

Manager of Product Safety

sen Mess

Degussa Corporation - Product Regulatory Services

Product Manager

Degussa Corporation - Bleaching and Water Chemicals

Administrative

Materials

Whip

DP BARCODE: D286206 FQPA

CASE: 069188 DATA PACKAGE RECORD DATE: 10/16/02

SUBMISSION: S623448 BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 189 RESB FQPA-OC-ME TOO

CHEMICALS: 000595 Hydrogen peroxide 20.0000%

ID#: 071355-E CID 2000

COMPANY: 071355 CID LINES N.V.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9

RECEIVED DATE: 10/01/02 DUE OUT DATE: 01/29/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 286206 EXPEDITE: N DATE SENT: 10/16/02 DATE RET.: / /

CHEMICAL: 000595 Hydrogen peroxide

PP TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 01/19/03

DIV: AD // NEGOT DATE: //

BRAN: PSB // // PROJ DATE: //

SECT: EET // //

REVR: // //
CONTR: // //

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the Efficacy Data to support labeling claims (457670-01; -02 and -03).

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

CID LINES C/O OLIVIA D. LAIRD 501 SOUTH LINCOLN AVENUE STERLING, VA 20164

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/01/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

## Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

457670-00

September 27, 2002

Mr. Marshall Swindell, PM 33 Environmental Protection Agency Regulatory Management Antimicrobial Division (7510C) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

Subject: CID 2000

**EPA FILE SYMBOL 71355-E** 

Submission of additional data to support registration

Dear Mr. Swindell:

Attached hereto please find five (5) copies of the revised labeling containing our proposed uses along with the letter of authorization form our supplier to address your chemistry data concerns. Also included with this package are the supportive efficacy data which will address efficacy concerns for the product referenced. Additional data are still underway and will be submitted after upon completion.

Please note, the efficacy date was conducted on what is potentially one of our additional brand names for this product. Rest assured that the formula is the same. Letter from the registrant is attached to the study as well to address any concerns you or the reviewers may bave concerning the name on the study.

Thank you for your help in this matter. Should you have any questions or concerns please don't hesitate to let me know.

Sincerely,

Olivia D. Laird President/Agent

#### TRANSMITTAL DOCUMENT

#### 1. NAME AND ADDRESS OF SUBMITTER & SPONSOR

SUBMITTER
LAIRD'S REGULATORY CONSULTANTS, INC.
501 SOUTH LINCOLN AVENUE
STERLING, VIRGINIA 20164-2024

**SPONSOR** 

NV CID LINES S.A. WATERPOORTSTRAAT 2 8900 IEPER, BELGIUM

#### 2. REGULATORY ACTION TO BE TAKEN

**Submission of Additional Efficacy Data** 

EPA FILE SYMBOL/REG. NO.: 71355-E

PRODUCT NAME: CID 2000(primary name)/Kickstart(additional name)

TRANSMITTAL DATE

September 27, 2002

### 3. LIST OF SUMITTED STUDIES

**Volume 1: Administrative Materials** 

45767001Volume 2: Efficacy-against infectious bursal disease virus

45767002 Volume 3: Efficacy-AOAC Use Dilution, study #01-109138-11

45767003 Volume 4: Efficacy-AOAC Use Dilution, Study #01-109139-11

COMPANY OFFICIAL: 10r VINCENT CATRY

COMPANY CONTACT: OLIVIA D. LAIRD

Phone: (703) 471-6590

FAX: (703) 471-6269

vol. 2

This an ACCEPTED ubmission

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#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 0 6 2001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Olivia Laird, Agent for NV CID Lines SA Waterpoorstraat 2 B 8900 leper-Belgium

Subject: CID 2000

EPA File Symbol Number 71355-E

Your Submission Dated September 18th, 2001 EPA Received Date September 20th, 2001

#### Dear Ms. Laird:

The following application(s) submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the following reasons:

- Resubmit five (5) copies of corrected, revised product labeling
- FDA clearance letter was not submitted in support of the "Hatching Egg Sanitization" claim
- Efficacy data was not submitted in support of non-food contact surface sanitization claim
- A Data Matrix form was not submitted as per Agency's letter of 01/08/01

#### Major Deficiencies

- As per our letter of January 8th, 2001, the "Certification with Respect to Citation of Data" form must specify "Cite-All" or "Selective" by placing a check mark in one of the boxes.
   A revised data matrix form was not included in your submission packet of September 18th, 2001. As you are citing some data, provide a list of the companies you are offering to compensate.
- 2. A storage and stability study is required as part of the product chemistry submission. This study was not included with your submission packet of September 18th, 2001.

- 3. A revised, corrected Confidential Statement of Formula must be resubmitted to the Agency for our review. The Confidential Statement of Formula should be given in two parts. The first part or pre-reaction Confidential Statement of Formula should be given in composition of the product with all the active and inert ingredients along with any impurities that may have been formed in the reaction.
- 4. The names and addresses of all ingredient suppliers must be provided in the pre-reaction Confidential Statement of Formula. Also, the source of should be provided e.g., etc.
- Since Hatching Egg claims are considered FDA regulated drug claims, the Agency requests a FDA clearance letter to support these claims that appear on the submitted product labeling. If additional is needed, you should contact Dr. Woodrow Knight at FDA's Center for Veterinary Medicine at (301)-827-0219.

#### General Comments

Submit efficacy data for food contact surface sanitization to the Agency for our review.

The product labeling has not been conducted yet. Once the efficacy data has been reviewed, the labeling will be also.

Should you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33

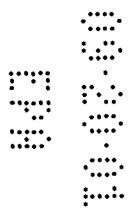
Regulatory Management Branch I Antimicrobial Division(7510C)

## Laird's Regulatory Consultants, Inc

Over 28 years Experience and Expertise in The Regulation of Pesticide Products

September 18, 2001

Mr. Marshall Swindell Environmental Protection Agency Regulatory Management Branch I Antimicrobial Division (7510C) Ariel Rios Building 1200 Pennsylvania Avenue, N.W. Washington, DC 20460



SUBJECT: CID 2000

EPA FILE SYMBOL 71355-E

Dear Mr. Swindell:

Please find attached hereto the revised label containing directions for use for hatching eggs for the product listed above per our discussions.

Thank you for your prompt attention.

Respectfully Yours,

Olivia D. Laird President/Agent

# CID 2000<sup>®</sup>

## CONCENTRATED SANITIZER FOR HATCHING EGGS

Active Ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients	26.5% 4.9% 68.6 % 100.0%	•••••
STRONG OXIDIZING AGENT KEEP OUT OF REACH OF CHILDREN DANGER	••••	
APPLICATION: CID 2000 is a peroxyacetic acid based sanitizer developed for sanitizing of halo	hing eggs.	••••

#### PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### FIRST AID STATEMENTS

tF iN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, getatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

#### **NOTE TO PHYSICIAN:**

Probable mucosal damage may contraindicate the use of gastric lavage.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use the product in a manner inconsistent with its labelling.

#### For senitizing of hatching eggs:

Prepare a solution of CID 2000 by diluting 1.0 ounce CID 2000 with 5 gallons of water. The solution should be equal to or warmer than the eggs, but not exceed 130°F. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly well all sholl surfaces. The solution should not be reused for sanibzing halching eggs.

#### NOTE:

This product at its use dilution is compatible with stainless steel and aluminium surfaces. If product in intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### STORAGE AND DISPOSAL:

Storage: Store in a cool, dry place in tightly closed container away from children. Keep containers closed when not in use. Keep container out of direct sunlight. Avoid temperatures below 23°F and above 86°F to maintain product quality. Avoid all contaminants, especially dirt, caustic, reducing agents and metals.

Disposat of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment systom in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate tocal, state, or Federal agency to determine proper procedures.

Disposal of container: Triple finse. Then offer for recycling or puncture and dispose in a sentiary landfill. Disposal by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor Intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and discialms all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use of handling of this product, wether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N°: 71355-xx EPA Est. N°: 71355-8EL-001

BATCH N°: see top / bottlom EXPIRY DATE: see top / bottom

Net contents : see top / bottom

Produced by:

CIO LINES NV/SA - Waterpoortstraat 2 -B 8900 IEPER - BELGIUM - EUROPE Phone: 011-32-57-217877 - Fax: 011-32-57-217879 www.cidiines.bo - cidiines@cidiines.be



# **CID 2000®**

#### CONCENTRATED SANITIZER FOR HATCHING EGGS

Active ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID Inert ingredients	26.5% 4.9% <u>68.6 %</u> 100.0%	•::
STRONG OXIDIZING AGENT KEEP OUT OF REACH OF CHILDREN DANGER	****	•
APPLICATION: CID 2000 is a peroxyacetic acid based sanitizer developed for sanitizing of hatc	hing eggs.	••••

#### PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### FIRST AID STATEMENTS

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

tF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, getatin solution, or if these are not available, drink large quantities of water. Avoid atcohol.

# NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

## **DIRECTIONS FOR USE:**

It is a violation of Federal law to use the product in a manner inconsistent with its labelling.

# For sanitizing of hatching eggs:

Prepare a solution of CID 2000 by diluting 1.0 ounce CID 2000 with 5 gallons of water. The solution should be equal to or warmer than the eggs, but not exceed 130°F. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces. The solution should not be reused for sanitizing hatching eggs.

# NOTE:

This product at its use dilution is compatible with stainless steel and aluminium surfaces. If product in intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### STORAGE AND DISPOSAL:

Storage: Store in a cool, dry place in tightly closed container away from children, Keep containers closed when not in use. Keep container out of direct sunlight. Avoid temperatures below 23°F and above 86°F to maintain product quality. Avoid all contaminants, especially dirt, caustic, reducing agents and metals.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Centrol Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted by prior to disposal. CtD 2000, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the tabel; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, weither or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N°: 71355-xx EPA Est. N°: 71355-BEL-001

Net contents : see top / bottom

Produced by:

CID LINES NV/SA - Waterpoortstraat 2 -B 8900 IEPER - BELGIUM - EUROPE Phone: 011-32-57-217877 - Fax: 011-32-57-217879 www.cidines.be - ciclines@cidlines.be



# **CID 2000<sup>®</sup>**

## CONCENTRATED SANITIZER FOR HATCHING EGGS

Active ingredients: HYDROGEN PEROXIDE PEROXYACETIC ACID inert ingredients	26.5% 4.9% 68.6 % 100.0%	•••••
STRONG OXIDIZING AGENT KEEP OUT OF REACH OF CHILDREN DANGER	••••	
APPLICATION: CID 2000 is a peroxyacetic acid based sanilizer developed for sanitizing of hatch	hing eggs.	••••

#### PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an onclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### FIRST AID STATEMENTS

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical altention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

## NOTE TO PHYSICIAN :

Probable mucosal damage may contraindicate the use of gastric lavage.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use the product in a manner inconsistent with its labelling.

#### For sanitizing of hatching eggs:

Prepare a solution of CID 2000 by diluting 1.0 ounce CID 2000 with 5 gallons of water. The solution should be equal to or warmer than the eggs, but not exceed 130°F. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces. The solution should not be reused for sanitizing hatching eggs.

#### NOTE:

This product at its use dilution is compatible with stainless steel and aluminium surfaces. If product in intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### STORAGE AND DISPOSAL:

Storage: Store in a cool, dry place in tightly closed container away from children. Keep containers closed when not in use. Keep container out of direct sunlight. Avoid temperatures below 23°F and above 86°F to maintain product quality. Avoid all contaminants, especially dirt, caustic, reducing agents and metals.

Disposal of pesticide: Pesticide wastes are acutety hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted by grior to disposal. CID 2000, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures. Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National collisional containing this product to sever systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor Intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, wether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N°: 71355-xx EPA Est. N°: 71355-BEL-001

BATCH N\*: see top / bottom EXPIRY DATE: see top / bottom

Net contents : see top / bottom

Produced by:

CIO LINES NV/SA - Waterpooristraat 2 -B 8900 IEPER - BELGIUM - EUROPE Phone: 011-32-57-217877 - Fax: 011-32-57-217879 www.cldiines.be - cidiines@cidiines.be



# CID 2000<sup>®</sup>

## CONCENTRATED SANITIZER FOR HATCHING EGGS

Active ingredients:		
HYDROGEN PEROXIDE	26.5%	
PEROXYACETIC ACID	4.9%	
Inert ingredients	68.6 %	. • • •
·	100.0%	
STRONG OXIDIZING AGENT		• • • •
KEEP OUT OF REACH OF CHILDREN	٠٠٠:٠٠	•
DANGER	• • •	***
D) 11 0 2 11	****	
	****	•
APPLICATION:	•••••	•
CID 2000 is a peroxyacetic acid based sanitizer developed for sanitizing of hat	ching eggs.	••••

#### PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### FIRST AID STATEMENTS

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid atcohol.

#### NOTE TO PHYSICIAN:

Probable mucosat damage may contraindicate the use of gastric lavage.

## **DIRECTIONS FOR USE:**

It is a violation of Federal law to use the product in a manner inconsistent with its labelling,

#### For sanitizing of hatching eggs:

Prepare a solution of CID 2000 by diluting 1.0 ounce CID 2000 with 5 gallons of water. The solution should be equal to or warmer than the eggs, but not exceed 130°F. As eggs are gathered or prior to solting, apply solution as a coarse spray so as to lightly wet all shell surfaces. The solution should not be reused for sanitizing hatching eggs.

#### NOTE

This product at its use dilution is compatible with stainless steel and aluminium surfaces. If product in intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### STORAGE AND DISPOSAL:

Storage: Store in a cool, dry place in tightly closed container away from children. Keep containers closed when not in use, Keep container out of direct sunlight. Avoid temperatures below 23°F and above 86°F to maintain product quality. Avoid all contaminants, especially dirt, caustic, reducing agents and metals.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to tabet instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted by grior to disposal. CID 2000, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by State and local authorities, by burning, If burned, stay out of smoke.

## **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, wether or not such liability is based in the contract, negligence, strict liability in fort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N° : 71355-xx EPA Est. N° : 71355-8EL-001

BATCH No : see top / bottlom EXPIRY DATE : see top / bottom

Net contents : see top / bottom

Produced by:

CID LINES NV/SA - Waterpoortstraat 2 -B 8900 IEPER - BELGIUM - EUROPE Phone: 011-32-57-217877 - Fax: 011-32-57-217879 www.ciclines.be - ciclines@ciclines.be



# **CID 2000**<sup>®</sup>

## CONCENTRATED SANITIZER FOR HATCHING EGGS

ACTIVE	ingrecients :
	HYDROGEN PEROXIDE
	PEROXYACETIC ACID
Inert in	gredlents
	•

26.5%
4.9%
68.6 %
100.0%

# STRONG OXIDIZING AGENT KEEP OUT OF REACH OF CHILDREN DANGER

#### **APPLICATION:**

CID 2000 is a peroxyacetic acid based sanitizer developed for sanitizing of hatching eggs.

#### **PRECAUTIONARY STATEMENTS**

HAZARO TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before rouse.

#### FIRST AID STATEMENTS

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLDWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

#### **NOTE TO PHYSICIAN:**

Probable mucosal damage may contraindicate the use of gastric lavage.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use the product in a manner inconsistent with its labelling.

# For sanitizing of hatching eggs:

Prepare a solution of CID 2000 by diluting 1.0 ounce CID 2000 with 5 gallons of water. The solution should be equal to or warmer than the eggs, but not exceed 130°F. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces. The solution should not be reused for sanitizing hatching eggs.

#### NOTE:

This product at its use dilution is compatible with stainless steel and aluminium surfaces. If product in intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

#### STORAGE AND DISPOSAL:

Storage: Store in a cool, dry place in tightly closed container away from children. Keep containers closed when not in use. Keep container out of direct sunlight. Avoid temperatures below 23°F and above 86°F to maintain product quality. Avoid all contaminants, especially dirt, caustic, reducing agents and metals.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or ninsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to tabel instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance. If materiat has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted by prior to disposal. CID 2000, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanilary landfill. Disposal by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

## **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solety responsible for, any and all loss or camage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or selfer's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, wether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. N° : 71355-xx EPA Est. N° : 71355-BEL-001

Net contents : see top / bottom

Produced by:

CID LINES NV/SA - Waterpoortstraat 2 -B 8900 IEPER - BELGIUM - EUROPE Phone: 011-32-57-2 t7877 - Fax: 011-32-57-217879 www.cidlines.be - cidlinos@cidlines.be



SUBMISSION BAR CO	DE # <u>537</u>	85959	REVIE	ewer <u>K.Lcav</u>	y-Mun K
CODING FORM FOR A	PPLICAT	IONS FOR	REGISTE	MA\NOITA	ENDMENTS
file symbol/reg no. 7/			AC	CTION CODE_	188
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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 26460

JAN 0 8 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NV CID Lines SA Waterpoorstraat 2 B 8900 Ieper Belgium

Attention: Olivia Laird

Subject: CID 2000

EPA File Symbol Number 71355-E

Your Application Dated August 28th, 2000 EPA Received Date September 12th, 2000

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is unacceptable for the following reasons:

# ADMINISTRATIVE:

The "Certification with Respect to Citation of Data" form is incomplete. Under the "Method of Support" section of the "Certification with Respect to Citation of Data" form, please specify "Cite-All" or "Selective" by placing a check mark in one of the boxes.

The submitted data matrix is incomplete. The efficacy data must be listed on the data matrix in order to support any efficacy claims that appear on the product labeling. You must also submit a data matrix to support both technical grad active ingredients.

# CHEMISTRY:

The activator and stabilizer inert ingredients that are	typically found in perac-	etic acid
and hydrogen peroxide formulations, such as in the '	'Me-Too"	product,
were missing in the proposed CID 200 formulation.	The Agency requests co	onfirmation
whether the formulation indeed uses no activators or	stabilizers or whether a	n omission
of these inert ingredients has occurred in both the Co	onfidential Statement of	Formula,
as submitted, shows	as the supplier of perac	etic
acid. This is not consistent with the product chemist	ry data which describes	CID Lines

\*Manufacturing process information may be entitled to confidential treatment\*

Since CID 2000 is made by an integrated system, its Confidential Statement of Formula should be given in two parts. The first part or pre-reaction Confidential Statement of Formula should show the formula with all of the starting or beginning materials while the second part or post-reaction Confidential Statement of Formula should show the composition of the product with all the active and inert ingredients along with any impurities that may have been formed in the reaction.

The names and addresses of all ingredient suppliers must be provided in the pre-reaction Confidential Statement of Formula. Also, the source of the water should be provided e.g. municipal water, well water, deionized water, etc.

Since CID 2000 is made by an integrated system with non-registered ingredients, a five batch analysis and a storage and stability study is required as part of the product chemistry submission. This data was not provided.

In the discussion of the certified limits for the active ingredients in the chemistry data package, there are significant differences in these limits disclosed in the product chemistry data must support those given in the Confidential Statement of Formula.

However, the upper and lower certified limits for both the active and inert ingredients were acceptable as given in the Confidential Statement of Formula.

The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the basic formulation Confidential Statement of Formula agreed with the percentage declared on the product labeling.

All active and inert ingredients utilized in the formula are cleared for use in pesticide formulations.

# MINUTES OF THE MEETING:

On December 8th, 2000, Marshall Swindell (PM33) met with Luc Ledox (CID Lines Sales Manager), Helcna Brutsaert (CID Lines Export Consultant), Steve Diegnan (Merial Select, US Associate), Olivia Laird (Consultant).

We discussed the claims of the new application referenced above. The company was informed that the label contains a new use pattern: poultry drinking water(for use in drinking water lines). The Agency has an automatic processing time of nine moths for this new use.

Residue chemistry, efficacy(modify pool disinfection test protocol), toxicology data; and an FQPA Risk Assessment will be required to support the use pattern.

The company has decided to seek the poultry drinking water use pattern at another time. Currently, the company will seek a non-food contact surface sanitization claim for farm premises. The label will also include a "Hatching Egg Sanitization" claim.

The company was provided with a copy of DIS/TSS No. 3, 10, 15 and 18 enclosures. The company was informed that they must do the following:

- 1. must obtain FDA clearance to support the Hatching Egg Sanitization claim
- 2. must submit efficacy data to support the non-food contact surface sanitization label claim.
- 3. must submit five copies of revised product labeling.
- 4. are substantially similar in composition to the "Me-Too" product referenced on their application form; consequently, CID Lines may use the Cite-All option under the Selective method of support to satisfy their acute toxicity data requirements.

If you have any Questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell

Product Manager 33 Regulatory Management Branch I

Antimicrobial Division(7505C)

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

CID LINES C/O OLIVIA D. LAIRD 501 SOUTH LINCOLN AVENUE STERLING, VA 20164

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/12/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

#### TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

NV CID LINES SA Waterpoortstraat 2 B 8900 leper - Belgium

2. REGULATORY ACTION TO BE TAKEN

Submission for an application for registration of a Me-Too Product

Product Name: CID 2000

EPA FILE SYMBOL: 71355

3. TRANSMITTAL DATE

August 28, 2000

4. LIST OF SUBMITTED STUDIES

Volume 1. Administrative Materials

45210501 volume 2. CHEMISTRY DATA

Company Official:

Luc Ledoux

Company Name: CID LINES

Company Contact: Olivia D. Laird, Agent/Submitter

LAIRD'S REGULATORY CONSULTANTS

501 South Lincoln Avenue

Sterling, Virginia 20164-2024

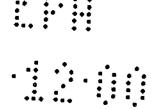
(703) 471-6590 phone \*Product ingredient source information may be entitled to confidential treatment\*

\*Inert ingredient information may be entitled to confidential treatment\*

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<b>SEPA</b>	ں Environmental	inited Stotes I Protection Agregion, DC 20450			Registration Amendmer Other	OPP Identifier Number
		Application for	Pesticide	- Section	1	
1. Company/Product No 71355-	amber E			uct Menager all Swin		3. Proposed Classification
4. Company/Product (N CID 20			PM#	33	-	None Restricted
NV CII Water 8900 I	of Applicant <i>Unclude ZIP Co</i> ) LINES SA  DOORTSTRAAT 2  Leper - Belgium  if this is a new address		(b)(i), my p to:	roduct is simi		with FIFRA Section 3(c)(3) in composition and labeling
Usì		Se.	ction - II	varie	4	
Notification - Explanation: Use as Applic Hydrog	n response to Agency letter tplein below. Iditional pagels) if nacessar	y. (For section 1 and 5 stration of d eviously rec	a Me-to along jistered	ency letter data le Too" Applica her - Explain be  O Produc with in product	t contain	ing Peracetic Acie dients which are Chemistry Data
			ction - III		······································	
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'd-Resistant Packag  tw	Yes No	No. par If "Yo		eging No. per container	Miles Pie	lainer etai estic ess per hor (Specify)
3. Location of Nat Con	tents Information  Container	4. Size(s) Reteil Cont  I Gallon		Z same	Cation of Label Di On Label On Labeling a	rections socompenying product
6. Manner in Which La	bel is Affixed to Product	Lithograph Paper glued Stenciled		Other		
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1. Contect Point ICom	piete items directly below f	or identification of ind	ividual to be co	ntacted, if nece	assery, to proces	s this spplication.)
1	Divia D. Laird tory Consultants,	Pre	sident/	gent	1	phone No (Include Area Code)
I certify that the I ecknowledge th both under appli	statements i have mede on hat any knowingly falsa or n çabla law.	Certification this form and all attac nisleading statement n	chments theret	o afe truo, accu cia by fins er in	trate and complet	te. 6. Data Application Received (Stamped)
2. Signature	Jaur	र्वे विभाव	ral Sale	s Manage	er:	
4. Typéd Name Luc Le	doux	5. Daie AUGU	ST 28. 3	2000		216







CID 2000 is a peracetic acid-based sanitizer developped for the cleaning and decontamination of drinking water systems for :

- 1. broilers and layers
- 2. turkeys
- 3. pigs

Active ingredients:

Peracetic acid Hydrogen peroxide Inert ingradients 5 % (by wt) 20 % <u>75 %</u> 100%

#### KEEP OUT OF REACH OF CHILDREN

# DANGER

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a targe quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

# SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No:

EPA Establishment No: 71355-BEL-001

Batch No : see top of bottle Expiry Date : see top of bottle

#### MANUFACTURED BY



Waterpoortstraat 2 - B-8900 tEPER BELGIUM - EUROPE Phone : 011 32 57 217877 - Fax : 011 32 57 217879

Website: http://www.cidlines.be - e-mail: cidlines@cidlines.be

Net contents: 1 gal

#### PRECAUTIONARY STATEMENTS

## HAZARD TO HUMANS AND DOMESTIC ANIMALS

latal if

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

# **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### PHYSICAL AND CHEMICAL HAZARDS:

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. CID 2000 is not combustible, however, at temperatures exceeding 158°F, decomposition-occurs releasing oxygen. The exygen released could initiate combustion.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CID 2000 peracetic acid sanitizer is recommended for use in drinking water systems a cleaning agent of the entire drinking water system (pipelines, nipples, bell-drinkers, ...) between the flocks, and as a drinking water sanitizer during production. CID 2000 is effective against bacteria and fungi and prevents formation of slimes during production.



Between the flocks: let circulate a 1:50 solution of CID 2000. Use circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of 4-6 hours. Drain thoroughly and rinse with potable water until clear water comes out of the drinking water system. Repeat treatment as required to maintain control.

For acidification and decontamination of the drinking water during production:
 Use CID 2000 at a dilution of 1:2500 to 1:3000 during 2 to 3 days a week every other day, or in delicate periods 3 to 4 consecutive days. Use circulation techniques as appropriate to the equipment.

Stop adding CID 2000 24 hours before vaccination and medical treatments.

#### REMARK:

Use CID 2000 with pumps fully made out of Teflon® (if not possible : make a 1:100 predilution before passing the pump)

#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chamical description on the label; (b) that this product is reasonable fit for the purposes set form in the cirections for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any apent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims as implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer state to solely responsible for, any and all less or camage which results from the use of this product in any manner which is inconsistent with the label directions, warrantes or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, wether or not such liability is based in the contract, negligence, strict liability in lot of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for; the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or setter be liable for special, indirect or consequential damages resulting from the use or handling of this product.



# TABLE OF CONTENTS

- 1. Transmittal Document
- 2. Application for Registration
- 3. Letter of Authorization
- 4. Offer To Pay Statement
- 5. Copy of CSF
- 6. Five (5) copies of revised labeling
- 7. Data Matrix

Form Accroved OMB No. 2070-0060



FRA.

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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Paperwork Reduction Act Notice: The public reporting burden for this collection of and 0.25 hours per response for reregistration and special review activities, including primerits regarding burden estimate or any other aspect of this collection of Information Management Division (2137), U.S. Environmental Protection Agency, 40 to not send the completed form to this address.	y time for reading the ation, including sugge	instructions and completing the necessary forms. Selections for reducing the burden to: Director, OPPE
Certification with Respec	t to Citation of	Data
Voplicant's/Registrant's Name, Address, and Telephone Number NV CID I Waterpoortstraat 2, 8900 Ieper - Belgiu	LINES SA um	EPA Registration Number/File Symbol 71355-
edive Ingredient(s) and/or representative test compound(s)  Eydrogen Peroxide and	acid,	Date August 28, 2000
Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 eterinary drinking water equipment sar	3) nitizer	Product Name CID 2000
TE: If your product is a 100% repackaging of another purchased EPA-registers is form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement)		rall the same uses on your label, you do not need to
I am responding to a Data-Call-in Notice, and have included with this form a be used for this purpose).	list of companies se	nt offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUPP	ORT (Check one me	etixed only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	the selective method of support (or cite-all option selective method), and have included with this form a list of data requirements (the Data Matrix form must b
SECTION II: GENERAL (	OFFER TO PAY	
Required if using the cite-all method or when using the cite-all option under the select	tive method to satisfy	one or more data requirements)
hereby offer and agree to pay compensation, to other persons, with regard to	the approval of this:	application, to the extent required by FIFRA
SECTION III: CERTI	IFICATION	
I certify that this application for registration, this form for reregistration, or the pplication for registration, the form for reregistration, or the Data-Call-in response. In idicated in Section I, this application is supported by all data in the Agency's files that ubstantially similar product, or one or more of the ingredients in this product; and (2) is equirements in effect on the date of approval of this application if the application soughests.	addition, if the cite-a t (1) concern the prop is a type of data that	If option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data
I certify that for each exclusive use study cited in support of this registration is written permission of the original data submitter to cite that study.	or reregistration, that	t I am the original data submitter or that I have obtaine
I certify that for each study cited in support of this registration or reregistration abmitter; (b) I have obtained the permission of the original data submitter to use the sempensation have expired for the study; (d) the study is in the public literature; or (e) I fixed (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) mount and terms of compensation, if any, to be paid for the use of the study.	itudy in support of this I have notified in writing	s application: (c) all periods of eligibility for ing the company that submitted the study and have

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any nowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

I certify that In all Instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in coordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are evailable and will be submitted to the Agency upon request. Should I fall to produce such vidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with

ignature Clinica A. Sound

Date

8/28/00

Typed or Printed Name and Title

Olivia D. Laird/Agent 221



# 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DAT	A MATRIX			
Dak August 28,	2000	······································	EPA Reg No.File Symbol 71355 -	<u> </u>	Page Lof 3
Applicant's/Registrant's Name & Addr NV CID LINES SA, W	ess Naterpoortstraat 2, B 8900 leper	-Belgium	Product CID 2000		
Ingradient Peracetic A	cid and Hydrogen Peroxide				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61 - 1 (830.1550)	Product Identity, Composition				
	and Analysis test guidelines	Attached	CID LINES	Own	
61-2 (830.1600-	Manufacturing Preocess				
830.1650)	Equipment used in process	Enclosed	CID LINES	Own	
62-1 (1830.1700 <del>-</del>	Preliminary Analysis				
1830.1750)				Own	-
62-2 (1830.1700-					
1830.1750)	Certified Limits	Enclosed	CID LINES	Own	
62 - 3(1830.1800)	Enforcement Analytical Method	Enclosed	CID LINES	Own	
63 - 2(830.7302)	Color	Enclosed	CID LINES	Own	
63 - 3(830.6303)	Physical State	Enclosed	CID LINES	Own	
63 - 4(830.6304)	Odor	Enclosed	CID LINES	Own	
63 - 5(830.7200)	Melting Point	N/A			
63 - 6(830.7220)	Boiling Point	Enclosed	CID LINES	Own	
63 - 7(830.7300)	Density/Bulk Density	Enclosed	CID LINES	Own	
Signature	Lauid		Name and Tide OLIVIA D. LAIRD, A	jent	Date 8/28/200(

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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	DAT	A MATRIX				
Date AU	GUST 28, 2000	EPA Reg No.:File Symbol 71355 —		Page <sub>2</sub> of 3		
Applicant's/Registrant's Name & Address NA CIDLINES SA, WATERPOORTSTRAAT 2, B 8900 Ieper- Belgium			Product			
ingredient	Peracetic Acid and Hydrogen	Peroxide				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
63 - 8(830.7840	Solubility	N/A				
and 830.7860						
63 - 9(830.7950)	Vapor Pressure	Enclosed	CID LINES	Own		
63 -10(830.7370)	Dissociation Constant	N/A				
63 -11(830.7570)	Octanol/Water Partition Coef.	N/A				
63 - 12(830.700u)	рн	Enclosed	CID LINES	Own		
63 -13(830.6313)	Stability	Enclosed	CID LINES	Own		
63 -14(830.6314)	Oxidizing Reducing Reaction	Enclosed	CID LINES	Own		
63 - 15(830.6315)	Flammability	Enclosed	CID LINES	Own		
63 - 16(830.6316)	Explodability	Enclosed	CID LINES	Own		
63 - 17(830.6317)	Storage Stability	Enclosed	CID LINES	Own		
63 -18(830.7100)	Viscosity	N/A				
63 -19(830.6319)	Miscibility	Enclosed	CID LINES	Own		
63 - 20(830.6320)	Corrosion Characteristic	NA				
63 -21(830.6321)	Dielectric Breakdown Voltage	N/A				
Signature	Day!		Name and Title OLIVIA D. LAIRD, AGE	:NT	Date 9/28/2000	

EPA Form 8576-95 (9-97) Electronic and Paper versions available. Submit only Paper version.

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information, including suggestions for reducing the burden to: Director, OPPE information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not

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send the form to this address. **DATA MATRIX** 71355 - = Date **AUGUST 28, 2000** EPA Reg No./File Symbol Pages of 2 Applicant's/Registrant's Name & Address Product NA CIDLINES SA, WATERPOORTSTRAAT 2, B 8900 Teper- Belgium CID 2000 Peracetic Acid and Hydrogen Peroxide ingredient Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note 81 - 1Acute Oral CITE-ALL 81 - 2Acute Dermal Irritation CITE-ALL 81 - 3(870.1300)Acute Inhalation Toxicity CITE-ALL 81 - 4Primary Eye Irritation CITE-ALL Dermal Sensitization 81 - 6CITE-ALL Name and Title Signature Date OLIVIA D. LAIRD, AGENT 9/28/200

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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**December 17, 1997** 

ENVIRONMENTAL PROTECTION AGENCY Regulatory Management Branch Antimicrobial Division Registration Division (H7505C) Office of Pesticide Programs 401 M Street, S.W. Washington D.C. 20460 U.S.A.

Dear Sir/Madam,

By this letter, I hereby authorize OLIVIA D. LAIRD doing business as

LAIRD'S REGULATORY CONSULTANTS, INC. 501 South Lincol Avenue Sterling, VA 20164-2024 U.S.A.

To deal with the Environmental Protection Agency in all matters pursuant to registration matters for our company.

This authorization is effective as of this date and will remain in effect until further notice.

Sincerely,

Jan-Jeroen De Beucker Area Sales Manager

CID Lines N.V. - Belgium

Waterpoortstraat 2 8900 IEPER - Belgium 12 +32[0]57 21 78 77 - Fax +32(0]57 21 78 79 B.T.W. BE 435.921.958

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Tel. 1001 32 5

EID-LINES F225



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of CID 2000

DP Barcode: D269345

Reg. No. or File Symbol: 71355-E

Manufacturing-use [ ]

End-use Product [X]

Active Ingredient Composition:

Peracetic acid......5%
Hydrogen peroxide......20%

TO:

Marshall Swindell PM33

FROM:

Alex Traska, Chemist

Rf 12/11/00

Aubel Dern

Product Science Branch, CT Team Antimicrobials Division (7510C)

THRU:

Karen P. Hicks, CT Team Leader

Product Science Branch

Antimicrobials Division (7510C)

THRU:

Michele E. Wingfield, Chief

Product Science Branch

Antimicrobials Division (7510 C)

# BACKGROUND:

This application for a new product registration, for the subject veterinary water system sanitizer, was submitted by Laird's Regulatory Consultant's, Inc. on behalf of the registrant, CID Lines N.V., Belgium.

The registrant, in this new product registration, has requested an expedited

\*Manufacturing process information may be entitled to confidential treatment\*

review of CID 2000 since the proposed product is similar to EPA

review of CID	2000 sinc	e the proposed product is similar to	EPA
Reg. No.		The	product,
	contains		

The following documents were submitted and examined in the chemistry review of this submission: application for a "me-too" product registration dated August 28, 2000, proposed Basic Formulation CSF dated 8/28/00, proposed product label dated 9/12/00 and product chemistry data for GRN 61, 62 and 63. Also examined for this review was the pending jacket file, No. 71355- E, for this product.

# FINDINGS:

- 1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the Basic Formulation CSF agreed with the percentage declared on the label.
- 2.Upper and lower certified limits for both the active and inert ingredients were acceptable as given in the CSF. However, in the discussion of certified limits for the active ingredients in the chemistry data package there are significant differences in these limits versus those given in the CSF. The certified limits disclosed in the product chemistry data must support those given in the CSF.
- 3.All active and inert ingredients utilized in the formula are cleared for use in pesticide formulations.
- 4. Certain activator and stabilizer inert ingredients that are typically found in peracetic acid and hydrogen peroxide formulations, such as in the "me-too" product, were missing in the proposed CID 2000 formulation. Registrant should confirm whether the formulation indeed uses no activators or stabilizers or whether an omission of these inert ingredients had occurred in both the CSF and product chemistry package.

5. The Basic Formulation CSF, as submitted, shows	
as the supplier of peracetic acid. This is not consistent with the pro-	duct
chemistry data which describes CID Lines, the registrant, as also the manufa	icturer
of peracetic acid. Peracetic acid is described as being made by	

\*Manufacturing process information may be entitled to confidential treatment\*

6. Since CID 2000 is made by an integrated system, its CSF should be given in two parts. The first part or pre-reaction CSF should show the formula with all of the starting or beginning materials while the second part or post-reaction CSF should show the composition of the product with all of the active and inert ingredients along with any impurities that may have been formed in the reaction.

7. The names and addresses of all	ingredient s	uppliers must be provided in the
pre-reaction CSF. Also the source	of the	should be provided e.g.
	etc.	

8. Since CID 2000 is made by and integrated system with non-registered ingredients, a five batch analysis and a storage stability study is required as part of the product chemistry submission. This data was not provided.

# **RECOMMENDATIONS:**

This application, for the new product registration of CID 2000, is not accepted.

Deficiencies noted under Findings should be corrected and all additional information requested should be provided.

12/11/00 AT

\*Inert ingredient information may be entitled to confidential treatment\*

12/11/200

Note to PM

Does the CID 2000 product label require a PR Notice 94-4 statement which the "me too" product was required to carry on its label?

Alex Traska





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

09/15/2000

OLIVIA D. LAIRD LAIRD'S REGULATORY CONSULTANTS, INC. 501 SOUTH LINCOLN AVE. STERLING VA 201642024

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: CID 2000

COMPANY NAME: LAIRD'S REGULATORY CONSULTANTS

OPP IDENTIFICATION NUMBER: 268976

EPA FILE SYMBOL: 71355-E EPA RECEIPT DATE: 09/12/2000

SUBJECT: RECEIPT OF APPLICATION FOR A NEW ME-TOO REGISTRATION

#### DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new 'me-too' registration and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Marshall Swindell, Product Manager 33, at (703)-308-6230.

Sincerely,

Aprice

Front End Processing Staff Information Services Branch

Program Management and Support Division

\*Product ingredient source information may be entitled to confidential treatment\* \*Inert ingredient information may be entitled to confidential treatment\* Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060 OPP Identifier Number Registration United States **Environmental Protection Agency** Amendment 268976 Washington, DC 20460 Other Application for Pesticide - Section I 2. EPA Product Menager 1. Company/Product Number 3. Proposed Classification 71355-*F* Marshall Swindell Restricted PM# 4. Company/Product (Name) 33 CID 2000 5. Name and Address of Applicant (Include ZIP Code) Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling NV CID LINES SA Waterpoortstraat 2 EPA Reg. No. 8900 Teper - Belgium Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in response to Agency letter dated "Me Too" Application. Resubmission in response to Agency letter dated... Notification - Explain below. Other - Explain below. Explanation: Use additional page is) if necessary. (For section I and Section II.1 Application for registration of a Me-too Product containing Peracetic Acid Hydrogen Peroxide and along with inert ingredients which are also contained in previously registered products. The Chemistry Data is contained in volume 2 of this package. Section - III 1. Material This Product Will Be Packaged In: Water Soluble Peckeging J-Resistant Packeging Unit Packaging 2. Type of Container Matel Y\*\* Yes Plastio Glass Paper "Yes" No. per ertification must Unit Packeging wgt. container Package wgt container Other (Specify) be submitted 4. Size(s) Retail Conteiner 3. Location of Net Contents Information 5. Location of Label Directions On Label 1 Gallon Container On Labeling accompanying product Lithograph Paper glued Stenciled Other 6. Manner in Which Label Is Affixed to Product Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Olivia D. Laird Telephone No. (Include Area Code) Name Thresident/Agent Laird's Regulatory Consultants, Inc. (703)471-65906. Date Application Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisorment or both under applicable law. 2. Signatura tëteral Sales Manager 4. Typed Name AUGUST 28, 2000 Luc Ledoux

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PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of Information is estimated to everage 0.85 hour pearsponse, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completes regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and uso reregistration, amendment, resubmission, to applications for notifications, final printed labeling, raregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- f. Certification with Respect to Citation of Date IEPA Form 8570-29}. [If not exempted by 40 CFR f52.81 (b) f4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels median the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate sterage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Date - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Blook A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriete action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorized on from that party to act for them in registral matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 5. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical review.
  Your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a outrantly registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed lebeling, for roregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "rerogistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Containor Information) - This Section must be completed for all applications submitted in connection with naw registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be merketed.
- 2. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Skets) of Recall Container Specify the net contents of all retail containers for your product.
- 5. Theflion of Use Directions Indicate the location of the use directions for your product.
- 6: Manner in which tobel is affixed to product indicated the method product label is attached to retail container.

SEOFION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "re-coo," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Driv.

\*Inert ingredient information may be entitled to confidential treatment\*

\*Product ingredient source information may be entitled to confidential treatment\*

Please read instructions on reve	rse before completing form.		Form Approved,				
	United States	- Common Deliver	X	Registra	tion	OPP Identifier Number	
Environmental Protection Agend Washington, DC 20460					ent	268976	
	Applicatio	n for Pesticid	e - Section			A	
1. Company/Product Number 71.355- E		2. EPA PA	oduct Managar hall Swin	đell –	3. Pro	posed Classification	
4. Company/Product (Name) CID 2000	V	PM#	33	حسب		None Restricted	
5. Name and Address of Applicant (Include ZIP Code)  NV CID LINES SA  Watexpoortstraat 2  8900 leper - Belgium  Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No  Product Name				
		Section - II					
Amendment - Explain bel	e to Agency latter dated		Final printed label Agency letter date "Me Too" Applica	od tšon,	to	*	
Notification - Explain belo	IW.		Other - Explain be	łow.			
	ned in previously d in volume 2 of		ge.	**		• • • • • • • • • • • • • • • • • • • •	
1. Material This Product Will Be	Packaged in:		· · · · · · · · · · · · · · · · · · ·				
Vos. 7	No Packaging  Yes No "Yes" No pan it Packaging wgt.	Weter Soluble Pe Yes Ne Ne H*Yes* Package wgt	No. per container	2. Type of (	Metal Plestic Glass Paper Other (S		
3. Location of Net Contents Info  Label Conte	18 /18-2	teil Container	5, Lor	On Label On Label		ns panying product	
6. Menner in Which Label Is Affi	xed to Product Lithou Paper	glued led	Other				
	7	Section - IV				· · · · · · · · · · · · · · · · · · ·	
1377.44	ns directly below for identification D. Laird				·	<del></del>	
Name Offvia Lairu's Regulatory C		Tip to with the test	/Agent		1	No Alinciudo Area Codel 471-6590	
		all attachments the	hable by fine or in	nprisonment		6. Data Application Received (Gramped)	
4. Typed Name Luc Ledoux		5. Date . AUGUST 28,	2000	<del></del>		***** **** **** ****	

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- 1. Certification with Respect to Citation of Dara (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 lb] (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Fermulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any date submitted;
- 8. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submirred in the form of draft labels with all applications for new registration. Such draft labels make in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5,

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Blook A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been essigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this posticide as it will appear on the labet. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United Stotes must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical it your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to smand the registration only of a ourrently registered product (Amendment), for a resubmission in response to an Agency latter, for notifications to the Agency, for the automission of final printed labeling, for reregistration and for any other action that partains to a specific EPA-registered product. This section is not to be used for a new application for registration.

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SECTION III (Packaging and Container information) - This Section must be completed for all applications submitted in connection with new registration or applications amendments.

- 1. Type of Packaging Check the appropriate block if your product will be peckaged in the indicated packaging types.
- indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Conteiner Indicate type of container in which product will be merketed.
- 6. Location of Net Contents indicate the location of the net contents information for your product.
- 4. Sizele of Retail Conteiner Specify the net contents of all retail containers for your product,
- The Location of Use Directions indicate the location of the use directions for your product.
- 6. Manner in which libel is affixed to product indicated the method product label is atteched to retail container.

SPCTION IV (Centact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "ne-160," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

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\*Inert ingredient information may be entitled to confidential treatment\*

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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Certification with Respec	t to Citation of	Data
Applicant's/Registrant's Name, Address, and Telephone Number NV CID Waterpoortstraat 2, 8900 Ieper - Belgi	LINES SA um	EPA Registration Number/File Symbol 71355-
Active Ingredient(s) and/or representative test compound(s) Peracetuc Hydrogen Peroxide and	acid,	Date August 28, 2000
See Determ(s) (list all those claimed for this product using 40 CFR Part 150 eterinary drinking water equipment sa	<sup>8)</sup> nitizer	Product Name CID 2000
NOTE: If your product is a 100% repackaging of another purchased EPA-register tube as form. You must submit the Formulator's Exemption Statement (EPA For		or all the same uses on your label, you do not need to
I am responding to a Date-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	int offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUP	PORT (Check one m	nethod only)
I am using the cits-all method of support, and have included with this form a list of companies sent offers of companiestion (the Data Matrix form should be used for this purpose).	under the	g the selective method of support (or cits-as option selective method), and have included with this form a disst of data requirements (the Data Matrix form must be
SECTION II: GENERAL	OFFER TO PAY	
Required if using the cite-all method or when using the cite-all option under the select hereby offer and agree to pay compensation, to other persons, with regard to		•
SECTION III: CERT	IFICATION	
I certify that this application for registration, this form for reregistration, or the polication for registration, the form for reregistration, or the Data-Call-In response. In dicated in Section I, this application is supported by all data in the Agency's files the obstantially similar product, or one or more of the ingredients in this product; and (2) equirements in effect on the date of approval of this application if the application sould see	addition, if the cite- t (1) concern the pro is a type of data that	ell option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data
I certify that for each exclusive use study cited in support of this registration is written permission of the original data submitter to cite that study.	or renegistration, the	at I am the original data submitter or that I have obtained
I certify that for each study cited in support of this registration or reregistration is abmitter; (b) I have obtained the permission of the original data submitter to use the impensation have expired for the study; (d) the study is in the public literature; or (e) fered (l) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(nount and terms of compensation, if any, to be paid for the use of the study.	study in support of the have notified in wri	nts application; (c) all periods of eligibility for ting the company that submitted the study and have
I certify that in all instances where an offer of compensation is required, cor	ies of all offers to o	v compensation and evidence of their delivery in

gneture Clinia A. Sound B/28/00 Olivia D. Laird/Agent 240

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any

containce with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fall to produce such ridence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with

rowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.



PROFESSIONAL HYGIENE

December 17, 1997

ENVIRONMENTAL PROTECTION AGENCY Regulatory Management Branch Antimicrobial Division Registration Division (H7505C) Office of Pesticide Programs 401 M Street, S.W. Washington D.C. 20460 U.S.A.

Dear Sir/Madam,

By this letter, I hereby authorize OLIVIA D. LAIRD doing business as

LAIRD'S REGULATORY CONSULTANTS, INC. 501 South Lincol Avenue Sterling, VA 20164-2024 U.S.A.

To deal with the Environmental Protection Agency in all matters pursuant to registration matters for our company.

This authorization is effective as of this date and will remain in effect until further notice.

Sincerely,

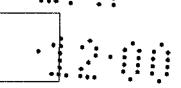
Jan-Jeroen De Beucker Area Sales Manager CID Lines N.V. - Belgium

enny

Waterpoortstraat 2 8900 IEPER - Belgium 2 +32(0|57 21 78 77 - Fax +32(0|57 21 78 79 B.T.W. BE 435.921.958

NV CID LINES
Widersoonston
8500 Jeber
Segum
Wil (20) 32 57
Fax (20) 32 5

## **CID 2000**



CID 2000 is a peracetic acid-based sanitizer developped for the cleaning and decontamination of drinking water systems for:

- f, broilers and tayers
- 2. furkeys
- 3. pigs

#### Active ingradients:

Peracetic acid Hydrogen peroxide Inert ingredients 5 % (by wt) 20 % <u>75 %</u> 100%

## KEEP OUT OF REACH OF CHILDREN

## DANGER

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON.SKIN: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical altention. Do not induce vomiting or give anything by mouth to an unconscious person. Orink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicale the use of gastric lavage.

## SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No : 7/355-E
EPA Eslablishmen! No : 71355-BEL-001

Satch No : see top of bottle Expiry Date : see top of bottle

#### MANUFACTURED BY:



Waterpoortstraat 2 - B 8900 IEPER BELGIUM - EUROPE

Phone: 011 32 57 217877 - Fax: 011 32 57 217879 Website: http://www.cidlines.be - e-mail: cidlines@cidlines.be

Net contents: 1 gal



#### HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an onclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

## **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Etimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### PHYSICAL AND CHEMICAL HAZARDS:

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be difuted in accordance with label directions prior to use. CID 2000 is not combustible, however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.



#### **DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

CtD 2000 peracetic acid sanitizer is recommended for use in drinking water systems as a cleaning agent of the entire drinking water system (pipolines, nipples, bell-drinkers, ...) between the flocks, and as a drinking water sanitizer during production.
CID 2000 is effective against bacteria and fungi and prevents formation of slimes during production.

1. Cleaning of drinking water systems:

Between the flocks: let circulate a 1:50 solution of CID 2000. Use circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of 4-6 hours. Drain thoroughly and rinse with potable water until clear water comes out of the drinking water system. Repeat treatment as required to maintain control.

2. For acidification and decontamination of the drinking water during production: Use CID 2000 at a dilution of 1:2500 to 1:3000 during 2 to 3 days a week every other day, or in delicate periods 3 to 4 consecutive days. Use circulation techniques as appropriate to the equipment.
Stop adding CID 2000 24 hours before vaccination and medical treatments.

#### REMARK:

Use CID 2000 with pumps fully made out of Teflon® (if not possible : make a 1:100 predilution before passing the pump)

#### **LIMITED WARRANTY AND DISCLAIMER:**

The manufacturar warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expent's evaluation of reasonable tests of effectiveness and of toxicity to taboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and discisints all implied warranties or merchanisability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the tabel directions, warnings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use of handling of this product, wether or not such liability is based in the contract, negligence, strict liability in the of otherwise, shell be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the user or handling of this product.

## **CID 2000**



CID 2000 is a peracetic acid-based saritizer developped for the cleaning and decontamination of drinking water systems for :

- 1. broilers and layers
- 2. turkeys
- 3. pigs

#### Active ingredients:

Peracetic acid Hydrogen peroxide inert ingredients 5 % (by wt) 20 % 75 % 100%

## KEEP OUT OF REACH OF CHILDREN

## DANGER

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flesh with a steady, gentle stream of water for 5 minutes. Get medical attention.

IF ON SKIN.: Rinse skin immediately with plenty of soap and water for 15-20 minutes. Get medical attention.

IF **SWALLOWED**: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

#### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No:

EPA Establishment No: 71355-BEL-001

Batch No : see top of bottle Expiry Date : see top of bottle

## MANUFACTURED BY:

CIDESTONAL NYGENE COMPANY

Waterpoortstraat 2 - B 8900 IEPER BELGIUM - EUROPE

Phone: 011 32 57 217877 - Fax: 011 32 57 217879 Website: http://www.cidlines.be - e-mail: cidlines@cidlines.be

Nøt contents : 1 gal

## PRECAUTIONARY STATEMENTS

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS



**DANGER.** CORROSIVE. Causes irreversible eye damage and skin burns. May be fatst if inhaled or absorbed through the skin. Harmfull if swallowed Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves when handling. Do not enter an enclosed area without proper repiratory protection.

Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into takes, streams, pends, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### PHYSICAL AND CHEMICAL HAZARDS:

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with tabel directions prior to use. CID 2000 is not combustible, however, at temperatures exceeding 158°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

#### DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

CID 2000 peracetic acid sanitizer is recommended for use in drinking water systems as a cleaning agent of the entire drinking water system (pipelines, rilpples, bell-drinkors, ...) between the flocks, and as a drinking water sanilizer during production. CID 2000 is effective against bacteria and fungi and prevents formation of slimes during production.



Between the flocks: let circulate a 1:50 solution of CID 2000. Use circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of 4-6 hours. Drain thoroughly and rinse with potable water until clear water comes out of the drinking water system. Repeat treatment as required to maintain control.

For acidification and decontamination of the drinking water during production:
 Use CID 2000 at a dilution of 1:2500 to 1:3000 during 2 to 3 days a week every other day, or in delicate periods 3 to 4 consocutive days. Use circulation techniques as appropriate to the equipment.

Stop adding CID 2000 24 hours before vaccination and medical treatments.

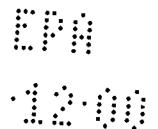
#### REMARK:

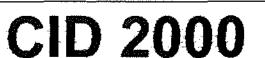
Use CID 2000 with pumps fully made out of Tellon® (if not possible : make a 1:100 preditution before passing the pump)

#### LIMITED WARRANTY AND DISCLAIMER:

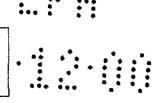
The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is masonable fit for the purposes self forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all steles or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agont or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and litness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or camage which results from the use of this product in any manner which is inconsistent with the label directions, warmings or cautions.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, welfer or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.









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- 1. broilers and layers
- 2. turkeys
- 3. pigs

#### Active ingredients:

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## DANGER

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NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

#### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No :

EPA Establishment No: 71355-BEL-001

Batch No : see top of bottle Expiry Date : see top of bottle

## MANUFACTURED BY:

CHOCKESSICHAL HYCKENIC COMPANY

Waterpoortstraat 2 - B 8900 IEPER BELGIUM - EUROPE

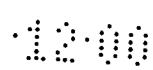
Phone: 011 32 57 217877 - Fax: 011 32 57 217879 Websile: http://www.cidlines.be - o-mail: cidlines@cidlines.be

Net contents: 1 gal

#### PRECAUTIONARY STATEMENTS

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS





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Wash thoroughly with soap and water after handling and before eating, drinking, or using lobacco. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS:**

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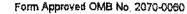
#### REMARK:

Use CID 2000 with pumps fully made out of Teflon® (if not possible : make a 1:100 predilution before passing the pump)

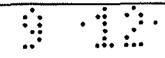
#### LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label: (b) that this product is reasonable fit for the purposes set both in the directions for use when it is used in accordance with such directions; and (c) that the directions, warrings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither-makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and discisions all implied warranties or merchantability and fitness for perticular purpose. This warranty does not extend to, and the buyer stast be solarly responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warrants or cautions.

Buyer's exclusive remady and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, wether or not such liability is based in the contract-negligence, strict liability in tort of etherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damaged are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.







## VNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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DATA MATRIX							
Date August 28, 2000			EPA Reg No./File Symbol	71355 <i>-E</i>	Page 1 <sub>of</sub> 3		
Applicant's/Registrant's Name & Address			Product				
NV CID LINES SA, Wa	terpoortstraat 2, B 8900 Teper-	-Belgium	CID 20	CID 2000			
Ingredient Peracetic Acid and Hydrogen Peroxide							
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
61 - 1 (830.1550)	Product Identity, Composition						
	and Analysis test guidelines	Attached	CID LINES	Own			
61-2 (830.1600-	Manufacturing Precess						
830.1650)	Equipment used in process	Enclosed	CID LINES	Own			
62-1 (1830.1700-	Preliminary Analysis						
1830.1750)				Own			
62-2 (1830.1700-							
1830.1750)	Certified Limits	Enclosed	CID LINES	Own			
62 - 3(1830.1800)	Enforcement Analytical Method	Enclosed	CID LINES	Own			
63 - 2(830.7302)	Color	Enclosed	CID LINES	Own			
63 - 3(830.6303)	Physical State	Enclosed	CID LINES	Own			
63 - 4(830.6304)	Odor	Enclosed	CID LINES	Own			
63 - 5(830.7200)	Melting Point	N/A					
63 - 6(830.7220)	Boiling Point	Enclosed	CID LINES	Own			
63 - 7(830.7300)	Density/Bulk Density	Enclosed	CID LINES	Own			
§ignature	Lauig	Name and Title  OLIVIA D. Li	aird, agent	Date <b>8/26/2000</b>			





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## D STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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**DATA MATRIX** 

Date August 20, 2003  Applicant's/Registrant's Name & Address  AV CID LIMBO DA, Haterpoortotraat 2, 8 8909 Teper-Belgium			EPA Reg No /File Symbol 713	Page of 3	
			Product CIP 2000		
ngredient Peracetic A	cio and mydrogen Peroxide				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61 - 1 (630.1550)	Product Identity, Composition				
	and Analysis test guidelines	Attached	CID LINGS	Own	
62-2 (000.2600-	Maguiacturing Precess				
830.1656)	Lalineat used in process	Enclose:		Oven	
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1030.1750)				Own	
62-2 (1030,1700-					
1630-1750)	Certifleo Liolto	Suciosed	Contract to the state of the	Own	
52 - 3(1850,1890)	Enforcement Analytical Method	Enclosed	CIS CINES	Car	:
65 - 2(836.7302)	Coior	Enclosed	CIP DIRES	0.42	
65 - 3(820.6303)	Physical State	Enclosed	CID LINES	Own	
63 - 4(630.6304)	ÚC G E	Enclosed	CID LINES	Own	
65 - 5(830.7200)	delting Point	R/2			<u> </u>
63 - 5(030.7220)	Boiling Point	Enclosed	CIN LINES	Own	
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Form Approved OMB No. 2070-0080

D STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice. The public reporting burden for this collection of information is estimated to average 0.25 hours per response for response for response for respiration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including the burden to Director, OPPE, information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20450. Do not send the form to this address.

		DATA	DATA MATRIX		
a a	August 20.	2992		EPA Reg No./File Symbol 71355	Page <sup>3</sup> of §
Applicant's/Regin	Applicant s/Registrant's Name & Address	89		Preduct	
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Ingredient	Peracetic A	Acid and Hydrogen Peroxide	-		
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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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NETRICTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers forces to pay have been early all data submitted or cited and all submitters from whom permission has been received or to whom offers forces to be a submitted or cited and all submitters from whom permission has been received or to whom offers forces to be a submitted or cited and all submitted or c mater (photocopy and attach additional pages as necessary). Complete all columns; ornission of essential information wall datay approval of the registration feregularity. On each page enter the data, Applications and name, EPA Registration Number or application the symbol of the product, ingredient, page marker, and total number of pages. The Cata Compensation Form series of Certification with Respect to Chalcon of Data" and the Data Matrix will be publicly available, except for the Guideline Number, Condesine Study Name, and MRID Number columns after the registration were greated of this product has been granted or once this form is received in response to a Data-Call-in Notice. However, the information in the Cuideline Retrence Number, Guideline Study Marine, and MRID Number columns is available through the Freedom of Information Ad in association with the EPA Registration Number.

Been a res Ingradient: Identify the active ingredients) in this product for which data are cited. The active ingredient is never the ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical representative test compound are cited, enter the identity of that chemical representative test compound including the EPA Registration Numberifile Symbol if appropriate.

ofe-at method is used for a particular Guideline Reference Mumber enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Mumber. In edition case, enter all submitters If the cite-all mathod is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Caldeline Reference Number column and beave the Cuideline Study Name column blank. If o whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Cuideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise

Quideline Reference Manhell. Enter on separate lives in numerical order the Guideline Reference flumbers from 40 CFR Part 158 for all studies cited to support the registration-front since the contract of the registration for this

Guideline Study Name: For each Guideline Reference Minnber cited, enter the corresponding Guideline Study Manne

Document Management System (PDMS). Enter only one MRID Mumber on each line. Note that more than one MRID Number may be required per Guideline Reference Mumber. Note: Occasionally MEND Manher: For each individual study cled in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (ARRID) Number listed in the Pesticide active to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study (les) Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be tweed. Cheaty explain any variations (alternate addresses, data owners not on the Data Submillers List, etc.) in footnotes to this table.

Status. Enter one of the following codes for each study ched, as appropriate

OWN.

I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application. či X

have obtained the permission of the Original Data Submitter to use this study in support of this application.

PEP.

The study was submitted more than 15 years ago and all pariods of compensation have expired. 000

The study is in the public merature.

ä

I have notified in writing the Original Data Submitter or, if the citie-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA weations 3(c)(1)(F) and (b) to commence negotiations to determine the amount and terms of compensation, if any, PAK

to be paid for the use of the shuby (les)

This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

any with the formulator's exemption for the ingredient only. Other columns of this the should be marked "NA". However, if this product is to be registered from additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or clied here to support those uses.

if additional explanation is needed, enter a felicitie number in this column and altach the comesponding explanation.

SON I

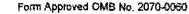




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DATA MATRIX							
Date AU	AUGUST 28, 2000			-	Page <sub>2</sub> of 3		
Applicant's/Registrant's Name & Addres	ss ATERPOORTSTRAAT 2, B 8900 leper	Page 2 of 3  Product  CID 2000					
Ingredient Peracetic Acid and Hydrogen Peroxide							
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
63 - 8(830.7840	Solubility	N/A					
and 830.7860							
63 - 9(830.7950)	Vapor Pressure	Enclosed	CID LINES	Own			
63 -10(830.7370)	Dissociation Constant	N/A					
63 -11(830.7570)	Octanol/Water Partition Coef.	N/A					
63 - 12(830.7000)	рн	Enclosed	CID LINES	Own			
63 -13(830.6313)	Stability	Enclosed	CID LINES	Own			
63 -14(830.6314)	Oxidizing Reducing Reaction	Enclosed	CID LINES	Own			
63 - 15(830.6315)	Flammability	Enclosed	CID LINES	Own			
63 - 16(830.6316)	Explodability	Enclosed	CID LINES	Own			
63 - 17(830.6317)	Storage Stability	Enclosed	CID LINES	Own			
63 -18(830.7100)	Viscosity	N/A					
63 -19 (830.6319)	Miscibility	Enclosed	CID LINES	Own			
63 - 20(830.6320)	Corrosion Characteristic	NA					
63 -21(830.6321)	Dielectric Breakdown Voltage	N/A					
Signature Signature			Name and Title OLIVIA D. LAIRD, AGE	NT	Date 9/28/2000		
	rank and Danar ranking Svallable Submit anty Panar version		<u> </u>	lernal Use Con	<del></del>		





## TED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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	DAT	A MATRIX			1	
Date Au	ICGST 28, 2000	EPA Reg No /File Symbol 71355		Page 2 of 3		
Applicant's/Registrant's Name & Address And CIDLIEDS on, WATERFOORTSTRAAT 3, 8 8900 Tener- Belgium			Product CIO 2008			
Ingredient Persontic Acid and Hydrogen Peroxi						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
63 - 6(830.7840	Solumnity	W/A				
and 230.7000						
63 - 9(330.7950)	Aghor Stevente	Enclosed		Own		
65 -10(330.7570)	Ulstociation Constant	M/A				
83 -11(830.7970)	Octamol/Water Partition Coef.	:5/3				
0.5 - 12(630.7600)		Enclosed	CID LINES	Own		
63 -13(630.6313)	stability	Enclosed	CID LIRES	Own		
vs -14(830+631+)	Oxidizing Reducing Resurion	Enclosed	CID AINES	Own		
\$\$ - L5(\$3\$\$,\$2\$5)	Florability	Saclosed	CID LINDS	Own		
03 - 10(830.6316)	Skylodacility	Enclosed	CID LIKES	Own		
03 - 17(830.5317)	Storage Stability	Snolosed	CID LINES	Own		
63 -16(830.7100)	Viscosity	N/A				
63 -29(830.6329)	Miscibility	Enclosed	CID BIGG	Own		
(6118.018)62 - 28	Corrosion Characteristic	n'A				
63 -21(830.6321)	Dielectric Breakdown Voltage	W/A				
Signature 2			Name and Title OI.IVIA D. LAIRD, A	C. S. Flore	Date 9/28/2000	





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**DATA MATRIX** 

	₩/AB	A MATINA				
AUGUST 28, 2000  Applicant's/Registrant's Name & Address NA CIDLINES SA, WATERPOORTSTNAAT 2, B 8900 leper- Belgium			EPA Reg No./File Symbol 71355		Page ? of 3	
			Product CID 2000			
ingredient	Peracetic Acid and Hydrogen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
63 - 0(836.7840	Solubility	W/A		1/		
and \$30.7869					***	
63 - 2(830.7950)	Vapor Pressure	Ercloned	CID LINES	Own		
53 -10(830.7370)	Dissociation Constant	N/A				
63 -11(630.7570)	Octanol/Water Partition Coef.	N/A				
63 - 12(830.7000)	D3 :	Enclosed	CID LINES	Own		
-53 -13(830,6313)	Stability	Enclosed	CIO LIMES	Own		
63 -14(830.6314)	Oxidizing Reducing Reaction	Enclosed	CID LINES	Own		
85 = 23(838.6223)	Plassability	Snclosed	CIU LINES	Own		
63 - 18(830.6316)	Explodability	Znclosed	CIO LIMES	Own		
63 - 17(830.6317)	Storage Stability	Enclosed	CID LIMES	Own		
63 -18(830.7100)	Viscosity	M/A				
63 -19(830.6319)	Miscibility	Enclosed	CID MINES	Own		
62 - 20(830,6320)	Corrosion Characteristic	WA				
63 -21(830-6321)	Dielectric Brenkdown Voltage	77/A				
Signature			Name and Title OLIVIA D. LAIND,	ACENT	Date 9/28/2000	

:

MSTRUCTIONS: Hersin all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay been been to submitted or cited and all submitted in the attached. math, (photocopy and attach additional pages as necessary). Complete all columns, ormisation of each of each page enter the Applicant shapistrants name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages. The Data Compensation Form entitled "Certification with Respect to Castion of Data" and the Data Matrix will be publicly except for the Guideline Reference Number, Guideline Study Name, and MRID Number, columns as a registration with the Endowment of the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns as available through the Freedom of Information Act in association with the EPA Registration Number.

ingredient. Identity the active ingredient(s) in this product for which data are cited. The active ingredient part of the character compound are cited, enter the identity of that chemical page for each separate active ingredient for which data are cited. If this propriate, from a related chemical or representative test compound are cited, enter the identity of that chemical propriate test compound including the EPA Registration Number 7% Symbol if appropriate.

the cite-all method is used for a particular Glödeline Reference Number enter "CITE-ALL" in the NRIO Number column on the line for that Guideline Reference Number, in either case, enter all submittees to whoth offers to pay have been sent on subsequent lines. [Note: If the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] <u>Otherwise</u>. If the olderall method is used for all data supporting his particular ingredient, enter "CITE-ALL" in the Guideline Reference Mumber column and leave the Guideline Study Mame column blank.

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration frances from for this Ingredient

Guideline Study Name: For each Guideline Reference Number clied, enter the corresponding Guideline Study Name.

MRID Mander: For each individual study cled in support of a Cuideline Reference Munder and Cuideline Study Name, enter the Master Record Identification (MRID) Munder Insed in the Peaticide study required to maintain a registration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number; so the study required to maintain a registration report the MRID Number; so the study required to maintain a registration report to the MRID Number; so the study required to maintain a registration of the MRID Number; so the study required to maintain a registration of the MRID Number; so the study required to maintain a registration of the study required to maintain a registration of the registration of the study required to maintain a registration of the registration of the study required to maintain a registration of the registration of the study required to maintain a registration of the registrati Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number: Note:

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cleed. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnates to this table.

Status: Enter one of the following codes for each study cited, as appropriate.

OWN:

I have otherned written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

have obtained the permission of the Original Data Submitter to use this study in support of this application

The study was submitted more than 15 years ago and all periods of compensation have expired 0

The study is in the public Sterenties

..) a. I have notified in writing the Original Data Submitter or, if the otie-all method is used, all companies hated in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and of (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study lies. PAX

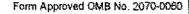
This Guideline data requirement is a data gap as defined in 40 CFR sections 152,83(a) and 152,96. CAQ.

Other columns of the ine should be marked "MA". However, if this product is to be registered free for additional uses for which the purchased EPA registered ingredient is not supported; additional date must be submitted or clerd here to support those uses. i arm taking the formulator's eventuation for this inquestions only.

Hackikonal explanation is needed, enter a footnicke number in this column and attach the corresponding explanation.

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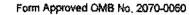




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	DAT	A MATRIX				
Date AU	GUST 28, 2000	EPA Reg No./File Symbol	Pagg of 3			
Applicant's/Registrant's Name & Address  NA CIDLINES SA, WATERPOORTSTRAAT 2, B 8900 Ieper- Belgium			Product CID 2000			
ingredient	Peracetic Acid and Hydrogen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
81 - 1	Acute Oral	CITE-ALL				
81 - 2	Acute Dermal Irritation	CITE-ALL				
81 - 3(870,1300)	Acute Inhalation Toxicity	CITE-ALL				
81 - 4	Primary Eye Irritation	CITE-ALL				
81 - 6	Dermal Sensitization	CITE-ALL				
**************************************						
<u> </u>						
Signature Signature	- Cand		Name and Title OLIVIA D. L	AIRD, AGENT	Date \$/28/2000	
V CD2 Corm \$570 36 (0 07) Elas	tranic and Canar varianc analesta Submit only Parar vargina		· <del>************************************</del>	Agancy Internal Use		





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MATE ....

	D	ATA MATRIX				
Date A	NCUST 26, 2000	Product CID 2000				
Applicant's Registrant's Name & Addi	ess MATERPOCKTSTRAAT 2, 5 8900 Ie;					
Ingredient	Peracetic Acid and Aydroge	a Peroxida				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
la in the six	Acute Oral	CITT-ALL				
\$\hat{\pi} = \hat{\pi}	Acute bermal Irritation	CITE-ALL				
01 - 3(670.1200)	Acute Inhalation Toxicity	CITE-ALL				
\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Primary Dye Stritation	CITE-ALL				
8.2 <b></b> 0	Dermai Sessitization	CINE-ALL				
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Signature D			Name and Title	IRO, ACTRIUT	Date 6/2#/9864	



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send the form to this address.					*	
1	DAT	A MATRIX				
Date &@	GUST 26, 2000		EPA Reg No./File Symbol 71355 -	<sub>Organ</sub> a. 	Page 3 of 2	
Applicant's/Registrant's Name & Addre	ss ATERPOORTSTRAAT 2, 8 8900 leper	- Belgium	Product CID 2000			
Ingredient	Jeraceric Acid and Bydrogen	Peroxida	Ę			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note .	
. 81 - 1	Acute Orax	CITT-ALL		#84 Jan 5 F. M	The state of the s	
81 - 2	Acute Dermal Irritation	CITE-ALL		, <b>j</b>	#	
32 - 3(870.1300)	Acute Inhalation Toxicity	CITE-ALD				
81 - 4	Primary Sye Irritation	CITE-ALL				
81 - C	Dermal Sensitization	CITE-NLL				
	·		***************************************			
	· · · · · · · · · · · · · · · · · · ·		. , , , , , , , , , , , , , , , , , , ,			
·		·				
Signature			Name and Title  GLIVIA D. LAIN, ACC		Date */2#/2000	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

#### INSTRUCTIONS FOR DATA MATRIX



INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns, ornission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Metrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-in Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(les).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN: I am the Original Data Submitter for this study.

EXC: I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

PER: I have obtained the permission of the Original Data Submitter to use this study in support of this application.

OLD: The study was submitted more than 15 years ago and all periods of compensation have expired.

PL: The study is in the public literature.

PAY: I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any.

to be paid for the use of the study(ies).

GAP: This Guideline data requirement is a data gap as defined in 40 CFR sections 152,83(a) and 152.96.

FOR: I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA", However, if this product is to be registered for additional

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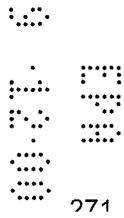
Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

## TABLE OF CONTENTS

- 1. Transmittal Document
- 2. Application for Registration
- 3. Letter of Authorization
- 4. Offer To Pay Statement
- 5. Copy of CSF
- 6. Five (5) copies of revised labeling
- 7. Data Matrix

Olivia D. Laird, President/Owner Laird's Regulatory Consultants, Inc. 501 South Lincoln Avenue Sterling, VA 20164-2024

Olivia D. Laird, President/Owner Laird's Regulatory Consultants, Inc. 501 South Lincoln Avenue Sterling, VA 20164-2024



, FIT

#### TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

NV CID LINES SA Waterpoortstraat 2 B 8900 Ieper - Belgium

2. REGULATORY ACTION TO BE TAKEN

Submission for an application for registration of a Me-Too Product

Product Name: CID 2000

EPA FILE SYMBOL: 71355

3. TRANSMITTAL DATE

August 28, 2000

4. LIST OF SUBMITTED STUDIES

Volume 1. Administrative Materials

Volume 2. CHEMISTRY DATA

Company Official:

Luc Ledoux

(signature)

Company Name: CID LINES

Company Contact: Olivia D. Laird, Agent/Submitter

LAIRD'S REGULATORY CONSULTANTS

501 South Lincoln Avenue

Sterling, Virginia 20164-2024

(703) 471-6590 phone

VO1, 1

272

